Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request: cder_mpl1r_wp159, Report 2 of 2

Request ID: cder_mpl1r_wp159_nsdp_v01

Request Description: We assessed the use patterns of ranitidine and a comparator agent, famotidine, within the Sentinel Distributed Database (SDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1

Data Source: We distributed this request to 16 Sentinel Data Partners on October 28, 2019.

Report 2 of 2: This report includes data from all Sentinel Data Partners except the Centers for Medicare and Medicaid Services (CMS). The study period includes data from January 1, 2000 through April 30, 2019. Please see Appendix A for a list of dates of available data for each Data Partner. See Report 1 for results from CMS.

Study Design: We identified individuals with incident and prevalent use of ranitidine and famotidine, and then characterized use and dispensing patterns by examining all episodes of use occurring after the initial exposure (index). This is a Type 5 analysis described in the Query Request Package (QRP) documentation.

Exposures of Interest: We defined the exposures of interest, ranitidine and famotidine, using outpatient dispensing data and National Drug Codes (NDCs). We applied a washout period to identify the first valid exposure episode of incident drug use; otherwise we assessed all valid exposure episodes during the query period. Please see Appendix B for a list of generic and brand drug names, and Appendix C for a list of Healthcare Common Procedure Coding System (HCPCS) codes used to define exposures and incidence criteria in this request.

Cohort Eligibility Criteria: We did not require any pre-treatment health plan enrollment for the prevalent cohorts. For incident cohorts, we required members to be continuously enrolled in health plans with medical and drug coverage in the 183 days prior to their index date, during which gaps in coverage of up to 45 days were allowed. Additionally, for the incident cohorts, we defined new use as no evidence of treatment with ranitidine, famotidine, cimetidine or nizatidine in the 183 days prior to their index date. The following age groups were included in the cohort: <2, 2-11, 12-17, 18-39, 40-64, and 65+ years. We formed the following six cohort groups for each of the two exposures of interest:

1. Prevalent cohorts with drug exposures administered in the form of oral solid or oral liquid;
2. Prevalent cohorts with drug exposures administered in the form of injection or intravenous;
3. Prevalent cohorts with drug exposures administered in the form of oral solid, oral liquid, injection or intravenous;
4. Incident cohorts with drug exposures administered in the form of oral solid or oral liquid;
5. Incident cohorts with drug exposures administered in the form of injection or intravenous;
6. Incident cohorts with drug exposures administered in the form of oral solid, oral liquid, injection or intravenous.

Baseline Characteristics: We characterized the following information on the index dispensing date: age, year, sex, whether the index drug was over-the-counter (OTC), and manufacturer of the index drug. In addition, we evaluated proton-pump inhibitor (PPI) use from the day after index until the end of follow-up. We identified PPI and all index drug use by NDCs and HCPCS codes. Please see Appendices D and E for a list of codes used to define baseline characteristics in this request.

Please see Appendices F and G for the specifications of parameters used in this request.

Limitations: Algorithms to define exposures, incidence criteria and baseline characteristics are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (https://dev.sentinelsystem.org/projects/sentinel/repos/sentinel-routine-querying-tool-documentation/browse).

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Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Module*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

- **Ambulatory Visit (AV) -** includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- **Emergency Department (ED) -** includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP) -** includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS) -** includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA) -** includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled” sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1a. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	4,330,042	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	39.0	23.8
Age (years)	**Number**	**Percent**
<2	701,599	16.2%
2-11	333,389	7.7%
12-17	174,101	4.0%
18-39	868,090	20.0%
40-64	1,387,629	32.0%
65+	865,234	20.0%
Sex	**Number**	**Percent**
Female	2,573,465	59.4%
Male	1,756,421	40.6%
Other	156	0.0%
Year	**Number**	**Percent**
2000	247,263	5.7%
2001	175,159	4.0%
2002	151,900	3.5%
2003	102,564	2.4%
2004	107,694	2.5%
2005	107,801	2.5%
2006	190,768	4.4%
2007	186,904	4.3%
2008	250,137	5.8%
2009	238,123	5.5%
2010	250,183	5.8%
2011	241,665	5.6%
2012	246,651	5.7%
2013	262,793	6.1%
2014	281,736	6.5%
2015	286,889	6.6%
2016	335,718	7.8%
2017	352,845	8.1%
2018	296,854	6.9%
2019	16,395	0.4%
Recorded dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	11,712	0.3%
PPI use, post-index (day 1 to the end of follow-up)	1,619,181	37.4%
Index date dispensing by manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	1,098,609	25.4%
Ahp	163	0.0%
Amneal Pharmace	601,856	13.9%
Apotex Corp	291,063	6.7%
Bedford Labs	51	0.0%
Boehringer Cons	3,084	0.1%
Boehringer/Chat	2,134	0.0%

Table 1a. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Index date dispensing by manufacturer (Ranitidine only):	Number	Percent
Chattem Cons Pr	5	0.0%
Covis Pharmaceu	140	0.0%
Covis/Teligent	25	0.0%
Dr.Reddy'S Lab	96,145	2.2%
Glaxo Pharm	51	0.0%
Glaxosmithkline	121,570	2.8%
Glenmark Pharma	402,845	9.3%
Gsms, Inc.	1,477	0.0%
Hi-Tech/Akorn C	112,132	2.6%
Major Pharmaceu	9,877	0.2%
Mylan	28,266	0.7%
Mylan Instituti	6,671	0.2%
Par Pharm.	654,584	15.1%
Pfizer Cons.Hlt	1,095	0.0%
Pharmaceutical	152,071	3.5%
Precision Dose	213	0.0%
Ranbaxy Pharmac	42	0.0%
Sandoz	265,325	6.1%
Silarx/Lannett	115,256	2.7%
Strides Pharma	1	0.0%
Teligent Pharma	21	0.0%
Teva Usa	702,998	16.2%
Watson Labs	1,394	0.0%
Wockhardt Usa L	104	0.0%
Zydus Pharmaceu	89	0.0%

[1]All metrics based on total number of unique patients

Table 1b. Aggregated Baseline Table for Ranitidine, Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	236,136	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	51.1	17.2
Age (years)	**Number**	**Percent**
<2	1,377	0.6%
2-11	5,121	2.2%
12-17	6,456	2.7%
18-39	48,663	20.6%
40-64	118,252	50.1%
65+	56,267	23.8%
Sex	**Number**	**Percent**
Female	152,842	64.7%
Male	83,274	35.3%
Other	20	0.0%
Year	**Number**	**Percent**
2000	371	0.2%
2001	580	0.2%
2002	709	0.3%
2003	963	0.4%
2004	2,173	0.9%
2005	2,749	1.2%
2006	9,026	3.8%
2007	10,543	4.5%
2008	22,198	9.4%
2009	21,976	9.3%
2010	20,209	8.6%
2011	26,182	11.1%
2012	17,224	7.3%
2013	19,071	8.1%
2014	24,088	10.2%
2015	22,191	9.4%
2016	19,967	8.5%
2017	7,082	3.0%
2018	8,599	3.6%
2019	235	0.1%
Recorded dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	13	0.0%
PPI use, post-index (day 1 to the end of follow-up)	82,011	34.7%
Index date dispensing by manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	2,852	1.2%
Ahp	0	0.0%
Amneal Pharmace	940	0.4%
Apotex Corp	587	0.2%
Bedford Labs	3,560	1.5%
Boehringer Cons	10	0.0%
Boehringer/Chat	6	0.0%

Table 1b. Aggregated Baseline Table for Ranitidine, Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Index date dispensing by manufacturer (Ranitidine only):	Number	Percent
Chattem Cons Pr	0	0.0%
Covis Pharmaceu	8,115	3.4%
Covis/Teligent	1,499	0.6%
Dr.Reddy'S Lab	35	0.0%
Glaxo Pharm	0	0.0%
Glaxosmithkline	36	0.0%
Glenmark Pharma	694	0.3%
Gsms, Inc.	5	0.0%
Hi-Tech/Akorn C	52	0.0%
Major Pharmaceu	19	0.0%
Mylan	1	0.0%
Mylan Instituti	26	0.0%
Par Pharm.	219	0.1%
Pfizer Cons.Hlt	4	0.0%
Pharmaceutical	53	0.0%
Precision Dose	0	0.0%
Ranbaxy Pharmac	0	0.0%
Sandoz	272	0.1%
Silarx/Lannett	39	0.0%
Strides Pharma	0	0.0%
Teligent Pharma	521	0.2%
Teva Usa	1,927	0.8%
Watson Labs	1	0.0%
Wockhardt Usa L	0	0.0%
Zydus Pharmaceu	5,105	2.2%

[1]All metrics based on total number of unique patients

Table 1c. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid or Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	4,530,789	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	39.6	23.8
Age (years)	**Number**	**Percent**
<2	702,434	15.5%
2-11	337,026	7.4%
12-17	179,377	4.0%
18-39	908,207	20.0%
40-64	1,490,830	32.9%
65+	912,915	20.1%
Sex	**Number**	**Percent**
Female	2,702,337	59.6%
Male	1,828,279	40.4%
Other	173	0.0%
Year	**Number**	**Percent**
2000	247,555	5.5%
2001	175,548	3.9%
2002	152,390	3.4%
2003	103,232	2.3%
2004	109,209	2.4%
2005	109,674	2.4%
2006	198,596	4.4%
2007	196,059	4.3%
2008	270,390	6.0%
2009	257,708	5.7%
2010	267,816	5.9%
2011	264,471	5.8%
2012	261,167	5.8%
2013	278,883	6.2%
2014	302,368	6.7%
2015	305,650	6.7%
2016	352,152	7.8%
2017	357,676	7.9%
2018	303,673	6.7%
2019	16,572	0.4%
Recorded dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	11,671	0.3%
PPI use, post-index (day 1 to the end of follow-up)	1,684,559	37.2%
Index date dispensing by manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	1,095,557	24.2%
Ahp	163	0.0%
Amneal Pharmace	598,675	13.2%
Apotex Corp	290,406	6.4%
Bedford Labs	3,344	0.1%
Boehringer Cons	3,078	0.1%
Boehringer/Chat	2,129	0.0%

Table 1c. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid or Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Index date dispensing by manufacturer (Ranitidine only):	Number	Percent
Chattem Cons Pr	5	0.0%
Covis Pharmaceu	7,630	0.2%
Covis/Teligent	1,431	0.0%
Dr.Reddy'S Lab	95,916	2.1%
Glaxo Pharm	51	0.0%
Glaxosmithkline	121,465	2.7%
Glenmark Pharma	400,707	8.8%
Gsms, Inc.	1,472	0.0%
Hi-Tech/Akorn C	112,007	2.5%
Major Pharmaceu	9,843	0.2%
Mylan	28,259	0.6%
Mylan Instituti	6,680	0.1%
Par Pharm.	654,019	14.4%
Pfizer Cons.Hlt	1,092	0.0%
Pharmaceutical	151,902	3.4%
Precision Dose	213	0.0%
Ranbaxy Pharmac	42	0.0%
Sandoz	264,480	5.8%
Silarx/Lannett	115,149	2.5%
Strides Pharma	1	0.0%
Teligent Pharma	464	0.0%
Teva Usa	699,809	15.4%
Watson Labs	1,389	0.0%
Wockhardt Usa L	104	0.0%
Zydus Pharmaceu	4,809	0.1%

[1]All metrics based on total number of unique patients

Table 1d. Aggregated Baseline Table for Famotidine, Oral Solid/Liquid (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	2,333,213	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	50.5	19.4
Age (years)	**Number**	**Percent**
<2	29,905	1.3%
2-11	41,134	1.8%
12-17	62,600	2.7%
18-39	609,422	26.1%
40-64	954,089	40.9%
65+	636,063	27.3%
Sex	**Number**	**Percent**
Female	1,419,784	60.9%
Male	913,290	39.1%
Other	139	0.0%
Year	**Number**	**Percent**
2000	14,202	0.6%
2001	16,250	0.7%
2002	53,922	2.3%
2003	102,856	4.4%
2004	98,536	4.2%
2005	102,012	4.4%
2006	129,355	5.5%
2007	124,093	5.3%
2008	128,653	5.5%
2009	119,940	5.1%
2010	127,259	5.5%
2011	121,200	5.2%
2012	124,538	5.3%
2013	139,140	6.0%
2014	155,827	6.7%
2015	163,238	7.0%
2016	194,188	8.3%
2017	212,322	9.1%
2018	196,960	8.4%
2019	8,722	0.4%
Recorded dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	7,664	0.3%
PPI use, post-index (day 1 to the end of follow-up)	840,433	36.0%

[1]All metrics based on total number of unique patients

Table 1e. Aggregated Baseline Table for Famotidine, Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	360,750	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	46.0	16.5
Age (years)	**Number**	**Percent**
<2	797	0.2%
2-11	4,201	1.2%
12-17	10,407	2.9%
18-39	115,774	32.1%
40-64	190,439	52.8%
65+	39,132	10.8%
Sex	**Number**	**Percent**
Female	235,966	65.4%
Male	124,779	34.6%
Other	5	0.0%
Year	**Number**	**Percent**
2000	111	0.0%
2001	160	0.0%
2002	399	0.1%
2003	671	0.2%
2004	1,214	0.3%
2005	1,807	0.5%
2006	3,692	1.0%
2007	4,719	1.3%
2008	10,406	2.9%
2009	14,297	4.0%
2010	18,128	5.0%
2011	16,123	4.5%
2012	20,457	5.7%
2013	27,692	7.7%
2014	30,162	8.4%
2015	39,671	11.0%
2016	52,906	14.7%
2017	63,989	17.7%
2018	53,705	14.9%
2019	441	0.1%
Recorded dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	5	0.0%
PPI use, post-index (day 1 to the end of follow-up)	97,897	27.1%

[1]All metrics based on total number of unique patients

Table 1f. Aggregated Baseline Table for Famotidine, Oral Solid/Liquid or Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	2,660,511	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	49.9	19.1
Age (years)	**Number**	**Percent**
<2	30,565	1.1%
2-11	44,914	1.7%
12-17	72,113	2.7%
18-39	714,604	26.9%
40-64	1,128,751	42.4%
65+	669,564	25.2%
Sex	**Number**	**Percent**
Female	1,633,603	61.4%
Male	1,026,765	38.6%
Other	143	0.0%
Year	**Number**	**Percent**
2000	14,303	0.5%
2001	16,384	0.6%
2002	54,255	2.0%
2003	103,337	3.9%
2004	99,471	3.7%
2005	103,450	3.9%
2006	132,493	5.0%
2007	128,097	4.8%
2008	138,354	5.2%
2009	133,421	5.0%
2010	144,165	5.4%
2011	136,100	5.1%
2012	143,319	5.4%
2013	164,650	6.2%
2014	183,373	6.9%
2015	199,380	7.5%
2016	242,151	9.1%
2017	269,882	10.1%
2018	244,887	9.2%
2019	9,039	0.3%
Recorded dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	7,628	0.3%
PPI use, post-index (day 1 to the end of follow-up)	926,381	34.8%

[1]All metrics based on total number of unique patients

Table 1g. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	2,778,587	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	43.9	21.5
Age (years)	**Number**	**Percent**
<2	86,058	3.1%
2-11	289,976	10.4%
12-17	148,184	5.3%
18-39	645,196	23.2%
40-64	998,766	35.9%
65+	610,407	22.0%
Sex	**Number**	**Percent**
Female	1,719,259	61.9%
Male	1,059,222	38.1%
Other	106	0.0%
Year	**Number**	**Percent**
2000	71,282	2.6%
2001	146,986	5.3%
2002	128,123	4.6%
2003	85,027	3.1%
2004	74,134	2.7%
2005	91,406	3.3%
2006	92,412	3.3%
2007	105,890	3.8%
2008	136,182	4.9%
2009	157,815	5.7%
2010	167,043	6.0%
2011	158,215	5.7%
2012	157,587	5.7%
2013	165,015	5.9%
2014	174,882	6.3%
2015	187,873	6.8%
2016	230,790	8.3%
2017	239,062	8.6%
2018	201,113	7.2%
2019	7,750	0.3%
Recorded dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	10,350	0.4%
PPI use, post-index (day 1 to the end of follow-up)	1,110,418	40.0%
Index date dispensing by manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	685,493	24.7%
Ahp	130	0.0%
Amneal Pharmace	455,090	16.4%
Apotex Corp	194,766	7.0%
Bedford Labs	37	0.0%
Boehringer Cons	2,613	0.1%
Boehringer/Chat	1,875	0.1%

Table 1g. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Index date dispensing by manufacturer (Ranitidine only):	Number	Percent
Chattem Cons Pr	4	0.0%
Covis Pharmaceu	95	0.0%
Covis/Teligent	18	0.0%
Dr.Reddy'S Lab	60,233	2.2%
Glaxo Pharm	31	0.0%
Glaxosmithkline	48,549	1.7%
Glenmark Pharma	311,730	11.2%
Gsms, Inc.	1,066	0.0%
Hi-Tech/Akorn C	37,140	1.3%
Major Pharmaceu	7,883	0.3%
Mylan	12,562	0.5%
Mylan Instituti	3,118	0.1%
Par Pharm.	442,228	15.9%
Pfizer Cons.Hlt	931	0.0%
Pharmaceutical	58,031	2.1%
Precision Dose	93	0.0%
Ranbaxy Pharmac	41	0.0%
Sandoz	181,198	6.5%
Silarx/Lannett	43,829	1.6%
Strides Pharma	1	0.0%
Teligent Pharma	15	0.0%
Teva Usa	509,170	18.3%
Watson Labs	1,064	0.0%
Wockhardt Usa L	79	0.0%
Zydus Pharmaceu	62	0.0%

[1]All metrics based on total number of unique patients

Table 1h. Aggregated Baseline Table for Ranitidine, Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	181,857	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	51.5	17.2
Age (years)	**Number**	**Percent**
<2	657	0.4%
2-11	3,995	2.2%
12-17	5,239	2.9%
18-39	36,299	20.0%
40-64	90,690	49.9%
65+	44,977	24.7%
Sex	**Number**	**Percent**
Female	117,194	64.4%
Male	64,646	35.5%
Other	17	0.0%
Year	**Number**	**Percent**
2000	119	0.1%
2001	376	0.2%
2002	498	0.3%
2003	694	0.4%
2004	1,436	0.8%
2005	2,044	1.1%
2006	4,500	2.5%
2007	7,601	4.2%
2008	13,821	7.6%
2009	18,170	10.0%
2010	16,581	9.1%
2011	21,405	11.8%
2012	13,548	7.4%
2013	15,145	8.3%
2014	19,146	10.5%
2015	18,084	9.9%
2016	15,911	8.7%
2017	5,740	3.2%
2018	6,859	3.8%
2019	179	0.1%
Recorded dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	12	0.0%
PPI use, post-index (day 1 to the end of follow-up)	62,633	34.4%
Index date dispensing by manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	2,314	1.3%
Ahp	0	0.0%
Amneal Pharmace	766	0.4%
Apotex Corp	449	0.2%
Bedford Labs	2,587	1.4%
Boehringer Cons	10	0.0%
Boehringer/Chat	5	0.0%

Table 1h. Aggregated Baseline Table for Ranitidine, Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Index date dispensing by manufacturer (Ranitidine only):	Number	Percent
Chattem Cons Pr	0	0.0%
Covis Pharmaceu	6,086	3.3%
Covis/Teligent	1,175	0.6%
Dr.Reddy'S Lab	27	0.0%
Glaxo Pharm	0	0.0%
Glaxosmithkline	20	0.0%
Glenmark Pharma	551	0.3%
Gsms, Inc.	4	0.0%
Hi-Tech/Akorn C	41	0.0%
Major Pharmaceu	16	0.0%
Mylan	1	0.0%
Mylan Instituti	22	0.0%
Par Pharm.	139	0.1%
Pfizer Cons.Hlt	4	0.0%
Pharmaceutical	46	0.0%
Precision Dose	0	0.0%
Ranbaxy Pharmac	0	0.0%
Sandoz	224	0.1%
Silarx/Lannett	25	0.0%
Strides Pharma	0	0.0%
Teligent Pharma	412	0.2%
Teva Usa	1,581	0.9%
Watson Labs	1	0.0%
Wockhardt Usa L	0	0.0%
Zydus Pharmaceu	3,896	2.1%

[1]All metrics based on total number of unique patients

Table 1i. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid or Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	2,943,890	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	44.3	21.3
Age (years)	**Number**	**Percent**
<2	86,662	2.9%
2-11	293,443	10.0%
12-17	152,868	5.2%
18-39	677,126	23.0%
40-64	1,082,259	36.8%
65+	651,532	22.1%
Sex	**Number**	**Percent**
Female	1,824,863	62.0%
Male	1,118,905	38.0%
Other	122	0.0%
Year	**Number**	**Percent**
2000	71,396	2.4%
2001	147,346	5.0%
2002	128,571	4.4%
2003	85,627	2.9%
2004	75,375	2.6%
2005	93,116	3.2%
2006	96,476	3.3%
2007	112,991	3.8%
2008	149,337	5.1%
2009	175,021	5.9%
2010	182,490	6.2%
2011	178,082	6.0%
2012	169,773	5.8%
2013	178,639	6.1%
2014	192,334	6.5%
2015	204,258	6.9%
2016	244,788	8.3%
2017	243,404	8.3%
2018	206,971	7.0%
2019	7,895	0.3%
Recorded dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	10,331	0.4%
PPI use, post-index (day 1 to the end of follow-up)	1,165,382	39.6%
Index date dispensing by manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	684,544	23.3%
Ahp	130	0.0%
Amneal Pharmace	453,484	15.4%
Apotex Corp	194,568	6.6%
Bedford Labs	2,530	0.1%
Boehringer Cons	2,611	0.1%
Boehringer/Chat	1,873	0.1%

Table 1i. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid or Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Index date dispensing by manufacturer (Ranitidine only):	Number	Percent
Chattem Cons Pr	4	0.0%
Covis Pharmaceu	5,961	0.2%
Covis/Teligent	1,158	0.0%
Dr.Reddy'S Lab	60,091	2.0%
Glaxo Pharm	31	0.0%
Glaxosmithkline	48,533	1.6%
Glenmark Pharma	310,628	10.6%
Gsms, Inc.	1,065	0.0%
Hi-Tech/Akorn C	37,119	1.3%
Major Pharmaceu	7,869	0.3%
Mylan	12,562	0.4%
Mylan Instituti	3,133	0.1%
Par Pharm.	442,084	15.0%
Pfizer Cons.Hlt	929	0.0%
Pharmaceutical	57,989	2.0%
Precision Dose	93	0.0%
Ranbaxy Pharmac	41	0.0%
Sandoz	180,866	6.1%
Silarx/Lannett	43,804	1.5%
Strides Pharma	1	0.0%
Teligent Pharma	390	0.0%
Teva Usa	507,848	17.3%
Watson Labs	1,063	0.0%
Wockhardt Usa L	78	0.0%
Zydus Pharmaceu	3,808	0.1%

[1]All metrics based on total number of unique patients

Table 1j. Aggregated Baseline Table for Famotidine, Oral Solid/Liquid (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	1,855,324	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	51.0	18.9
Age (years)	**Number**	**Percent**
<2	4,769	0.3%
2-11	33,246	1.8%
12-17	53,079	2.9%
18-39	482,399	26.0%
40-64	772,232	41.6%
65+	509,599	27.5%
Sex	**Number**	**Percent**
Female	1,133,185	61.1%
Male	722,014	38.9%
Other	125	0.0%
Year	**Number**	**Percent**
2000	3,852	0.2%
2001	10,274	0.6%
2002	39,439	2.1%
2003	83,442	4.5%
2004	83,134	4.5%
2005	87,423	4.7%
2006	93,621	5.0%
2007	97,695	5.3%
2008	98,267	5.3%
2009	101,042	5.4%
2010	105,213	5.7%
2011	99,533	5.4%
2012	101,033	5.4%
2013	109,341	5.9%
2014	119,327	6.4%
2015	130,663	7.0%
2016	157,538	8.5%
2017	170,315	9.2%
2018	159,168	8.6%
2019	5,004	0.3%
Recorded dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	6,365	0.3%
PPI use, post-index (day 1 to the end of follow-up)	661,567	35.7%

[1]All metrics based on total number of unique patients

Table 1k. Aggregated Baseline Table for Famotidine, Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	288,232	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	46.4	16.5
Age (years)	**Number**	**Percent**
<2	341	0.1%
2-11	3,363	1.2%
12-17	8,677	3.0%
18-39	89,040	30.9%
40-64	154,622	53.6%
65+	32,189	11.2%
Sex	**Number**	**Percent**
Female	187,987	65.2%
Male	100,242	34.8%
Other	3	0.0%
Year	**Number**	**Percent**
2000	49	0.0%
2001	105	0.0%
2002	248	0.1%
2003	490	0.2%
2004	900	0.3%
2005	1,425	0.5%
2006	2,208	0.8%
2007	3,577	1.2%
2008	6,384	2.2%
2009	11,626	4.0%
2010	14,612	5.1%
2011	13,129	4.6%
2012	16,467	5.7%
2013	21,978	7.6%
2014	23,344	8.1%
2015	31,905	11.1%
2016	42,662	14.8%
2017	52,265	18.1%
2018	44,491	15.4%
2019	367	0.1%
Recorded dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	4	0.0%
PPI use, post-index (day 1 to the end of follow-up)	77,035	26.7%

[1]All metrics based on total number of unique patients

Table 1l. Aggregated Baseline Table for Famotidine, Oral Solid/Liquid or Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019

Characteristic[1]	Number	Percent
Number of unique patients	2,128,162	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	50.4	18.7
Age (years)	**Number**	**Percent**
<2	5,105	0.2%
2-11	36,468	1.7%
12-17	61,340	2.9%
18-39	566,529	26.6%
40-64	919,552	43.2%
65+	539,168	25.3%
Sex	**Number**	**Percent**
Female	1,310,961	61.6%
Male	817,073	38.4%
Other	128	0.0%
Year	**Number**	**Percent**
2000	3,901	0.2%
2001	10,378	0.5%
2002	39,680	1.9%
2003	83,892	3.9%
2004	83,947	3.9%
2005	88,684	4.2%
2006	95,601	4.5%
2007	100,975	4.7%
2008	104,365	4.9%
2009	112,356	5.3%
2010	119,361	5.6%
2011	112,128	5.3%
2012	116,699	5.5%
2013	130,356	6.1%
2014	141,540	6.7%
2015	160,926	7.6%
2016	197,916	9.3%
2017	219,485	10.3%
2018	200,690	9.4%
2019	5,282	0.2%
Recorded dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	6,350	0.3%
PPI use, post-index (day 1 to the end of follow-up)	733,320	34.5%

[1]All metrics based on total number of unique patients

Table 2a. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, All Episodes, in Days, Overall

			Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposure	**Form**	**Design**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine	Oral	0-day washout, 0-day gap	4,330,042	100.0%	1,720,462	39.7%	604,561	14.0%	371,017	8.6%	593,809	13.7%	432,018	10.0%	608,175	14.0%
Ranitidine	Inj/IV[2]	0-day washout, 0-day gap	236,136	100.0%	233,448	98.9%	1,633	0.7%	473	0.2%	429	0.2%	115	0.0%	38	0.0%
Ranitidine	Any	0-day washout, 0-day gap	4,530,789	100.0%	1,911,868	42.2%	610,431	13.5%	372,029	8.2%	595,959	13.2%	432,225	9.5%	608,277	13.4%
Famotidine	Oral	0-day washout, 0-day gap	2,333,213	100.0%	959,133	41.1%	316,023	13.5%	137,086	5.9%	370,235	15.9%	225,015	9.6%	325,721	14.0%
Famotidine	Inj/IV	0-day washout, 0-day gap	360,750	100.0%	358,379	99.3%	1,297	0.4%	414	0.1%	447	0.1%	145	0.0%	68	0.0%
Famotidine	Any	0-day washout, 0-day gap	2,660,511	100.0%	1,277,707	48.0%	322,104	12.1%	138,096	5.2%	371,569	14.0%	225,214	8.5%	325,821	12.2%
Ranitidine	Oral	183-day washout, 30-day gap	2,778,587	100.0%	1,205,298	43.4%	318,804	11.5%	241,978	8.7%	376,906	13.6%	259,679	9.3%	375,922	13.5%
Ranitidine	Inj/IV	183-day washout, 30-day gap	181,857	100.0%	135,536	74.5%	15,441	8.5%	13,213	7.3%	13,908	7.6%	2,955	1.6%	804	0.4%
Ranitidine	Any	183-day washout, 30-day gap	2,943,890	100.0%	1,318,768	44.8%	337,064	11.4%	255,495	8.7%	392,083	13.3%	263,201	8.9%	377,279	12.8%
Famotidine	Oral	183-day washout, 30-day gap	1,855,324	100.0%	769,058	41.5%	229,793	12.4%	110,887	6.0%	313,105	16.9%	176,426	9.5%	256,055	13.8%
Famotidine	Inj/IV	183-day washout, 30-day gap	288,232	100.0%	254,512	88.3%	11,193	3.9%	10,636	3.7%	9,349	3.2%	1,933	0.7%	609	0.2%
Famotidine	Any	183-day washout, 30-day gap	2,128,162	100.0%	1,002,378	47.1%	244,580	11.5%	121,888	5.7%	323,424	15.2%	178,832	8.4%	257,060	12.1%

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

[2]Injection/Intravenous

Table 2b. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, All Episodes, in Days, by Sex

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	4,330,042	100.0%	1,720,462	39.7%	604,561	14.0%	371,017	8.6%	593,809	13.7%	432,018	10.0%	608,175	14.0%
Female	2,573,465	100.0%	1,016,310	39.5%	358,764	13.9%	222,190	8.6%	353,184	13.7%	258,510	10.0%	364,507	14.2%
Male	1,756,421	100.0%	704,091	40.1%	245,773	14.0%	148,812	8.5%	240,600	13.7%	173,495	9.9%	243,650	13.9%
Other	156	100.0%	61	39.1%	24	15.4%	15	9.6%	25	16.0%	13	8.3%	18	11.5%
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	236,136	100.0%	233,448	98.9%	1,633	0.7%	473	0.2%	429	0.2%	115	0.0%	38	0.0%
Female	152,842	100.0%	151,138	98.9%	1,050	0.7%	287	0.2%	277	0.2%	64	0.0%	26	0.0%
Male	83,274	100.0%	82,290	98.8%	583	0.7%	186	0.2%	152	0.2%	51	0.1%	12	0.0%
Other	20	100.0%	20	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Ranitidine, All (0-day washout, 0-day gap)	4,530,789	100.0%	1,911,868	42.2%	610,431	13.5%	372,029	8.2%	595,959	13.2%	432,225	9.5%	608,277	13.4%
Female	2,702,337	100.0%	1,138,860	42.1%	362,719	13.4%	222,874	8.2%	354,673	13.1%	258,637	9.6%	364,574	13.5%
Male	1,828,279	100.0%	772,931	42.3%	247,687	13.5%	149,140	8.2%	241,261	13.2%	173,575	9.5%	243,685	13.3%
Other	173	100.0%	77	44.5%	25	14.5%	15	8.7%	25	14.5%	13	7.5%	18	10.4%
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	2,333,213	100.0%	959,133	41.1%	316,023	13.5%	137,086	5.9%	370,235	15.9%	225,015	9.6%	325,721	14.0%
Female	1,419,784	100.0%	585,910	41.3%	191,246	13.5%	85,247	6.0%	225,919	15.9%	137,901	9.7%	193,561	13.6%
Male	913,290	100.0%	373,174	40.9%	124,761	13.7%	51,833	5.7%	144,281	15.8%	87,103	9.5%	132,138	14.5%
Other	139	100.0%	49	35.3%	16	11.5%	6	4.3%	35	25.2%	11	7.9%	22	15.8%
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	360,750	100.0%	358,379	99.3%	1,297	0.4%	414	0.1%	447	0.1%	145	0.0%	68	0.0%
Female	235,966	100.0%	234,389	99.3%	853	0.4%	276	0.1%	311	0.1%	87	0.0%	50	0.0%
Male	124,779	100.0%	123,985	99.4%	444	0.4%	138	0.1%	136	0.1%	58	0.0%	18	0.0%
Other	5	100.0%	5	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Famotidine, All (0-day washout, 0-day gap)	2,660,511	100.0%	1,277,707	48.0%	322,104	12.1%	138,096	5.2%	371,569	14.0%	225,214	8.5%	325,821	12.2%
Female	1,633,603	100.0%	793,787	48.6%	195,365	12.0%	85,929	5.3%	226,865	13.9%	138,030	8.4%	193,627	11.9%
Male	1,026,765	100.0%	483,867	47.1%	126,723	12.3%	52,161	5.1%	144,669	14.1%	87,173	8.5%	132,172	12.9%
Other	143	100.0%	53	37.1%	16	11.2%	6	4.2%	35	24.5%	11	7.7%	22	15.4%

Table 2b. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, All Episodes, in Days, by Sex

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,778,587	100.0%	1,205,298	43.4%	318,804	11.5%	241,978	8.7%	376,906	13.6%	259,679	9.3%	375,922	13.5%
Female	1,719,259	100.0%	733,874	42.7%	199,967	11.6%	153,099	8.9%	237,965	13.8%	163,557	9.5%	230,797	13.4%
Male	1,059,222	100.0%	471,384	44.5%	118,822	11.2%	88,867	8.4%	138,924	13.1%	96,112	9.1%	145,113	13.7%
Other	106	100.0%	40	37.7%	15	14.2%	12	11.3%	17	16.0%	10	9.4%	12	11.3%
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	181,857	100.0%	135,536	74.5%	15,441	8.5%	13,213	7.3%	13,908	7.6%	2,955	1.6%	804	0.4%
Female	117,194	100.0%	84,259	71.9%	10,258	8.8%	10,023	8.6%	10,064	8.6%	2,032	1.7%	558	0.5%
Male	64,646	100.0%	51,271	79.3%	5,182	8.0%	3,188	4.9%	3,837	5.9%	922	1.4%	246	0.4%
Other	17	100.0%	6	35.3%	1	5.9%	2	11.8%	7	41.2%	1	5.9%	0	0.0%
Ranitidine, All (183-day washout, 30-day gap)	2,943,890	100.0%	1,318,768	44.8%	337,064	11.4%	255,495	8.7%	392,083	13.3%	263,201	8.9%	377,279	12.8%
Female	1,824,863	100.0%	802,807	44.0%	212,122	11.6%	163,329	9.0%	248,893	13.6%	165,985	9.1%	231,727	12.7%
Male	1,118,905	100.0%	515,916	46.1%	124,926	11.2%	92,152	8.2%	143,166	12.8%	97,205	8.7%	145,540	13.0%
Other	122	100.0%	45	36.9%	16	13.1%	14	11.5%	24	19.7%	11	9.0%	12	9.8%
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,855,324	100.0%	769,058	41.5%	229,793	12.4%	110,887	6.0%	313,105	16.9%	176,426	9.5%	256,055	13.8%
Female	1,133,185	100.0%	469,880	41.5%	139,107	12.3%	69,250	6.1%	192,312	17.0%	109,417	9.7%	153,219	13.5%
Male	722,014	100.0%	299,134	41.4%	90,673	12.6%	41,632	5.8%	120,761	16.7%	66,998	9.3%	102,816	14.2%
Other	125	100.0%	44	35.2%	13	10.4%	5	4.0%	32	25.6%	11	8.8%	20	16.0%
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	288,232	100.0%	254,512	88.3%	11,193	3.9%	10,636	3.7%	9,349	3.2%	1,933	0.7%	609	0.2%
Female	187,987	100.0%	162,193	86.3%	8,072	4.3%	8,732	4.6%	7,156	3.8%	1,380	0.7%	454	0.2%
Male	100,242	100.0%	92,317	92.1%	3,121	3.1%	1,903	1.9%	2,193	2.2%	553	0.6%	155	0.2%
Other	3	100.0%	2	66.7%	0	0.0%	1	33.3%	0	0.0%	0	0.0%	0	0.0%
Famotidine, All (183-day washout, 30-day gap)	2,128,162	100.0%	1,002,378	47.1%	244,580	11.5%	121,888	5.7%	323,424	15.2%	178,832	8.4%	257,060	12.1%
Female	1,310,961	100.0%	618,003	47.1%	149,554	11.4%	78,198	6.0%	200,142	15.3%	111,123	8.5%	153,941	11.7%
Male	817,073	100.0%	384,329	47.0%	95,013	11.6%	43,684	5.3%	123,250	15.1%	67,698	8.3%	103,099	12.6%
Other	128	100.0%	46	35.9%	13	10.2%	6	4.7%	32	25.0%	11	8.6%	20	15.6%

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

Table 2c. Distribution of Patients' Cumulative Exposure Durationin the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, All Episodes, in Days, by Age Group

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	4,330,042	100.0%	1,720,462	39.7%	604,561	14.0%	371,017	8.6%	593,809	13.7%	432,018	10.0%	608,175	14.0%
<2 years	701,599	100.0%	277,235	39.5%	132,213	18.8%	77,706	11.1%	129,622	18.5%	67,071	9.6%	17,752	2.5%
2-11 years	333,389	100.0%	216,236	64.9%	47,408	14.2%	19,351	5.8%	27,994	8.4%	12,627	3.8%	9,773	2.9%
12-17 years	174,101	100.0%	98,445	56.5%	27,233	15.6%	12,489	7.2%	20,017	11.5%	9,055	5.2%	6,862	3.9%
18-39 years	868,090	100.0%	452,078	52.1%	134,223	15.5%	65,654	7.6%	101,323	11.7%	56,749	6.5%	58,063	6.7%
40-64 years	1,387,629	100.0%	464,470	33.5%	175,662	12.7%	114,780	8.3%	193,875	14.0%	164,485	11.9%	274,357	19.8%
65+ years	865,234	100.0%	211,998	24.5%	87,822	10.2%	81,037	9.4%	120,978	14.0%	122,031	14.1%	241,368	27.9%
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	236,136	100.0%	233,448	98.9%	1,633	0.7%	473	0.2%	429	0.2%	115	0.0%	38	0.0%
<2 years	1,377	100.0%	1,327	96.4%	25	1.8%	13	0.9%	5	0.4%	5	0.4%	2	0.1%
2-11 years	5,121	100.0%	5,049	98.6%	44	0.9%	11	0.2%	12	0.2%	2	0.0%	3	0.1%
12-17 years	6,456	100.0%	6,424	99.5%	17	0.3%	6	0.1%	4	0.1%	3	0.0%	2	0.0%
18-39 years	48,663	100.0%	48,510	99.7%	109	0.2%	27	0.1%	16	0.0%	1	0.0%	0	0.0%
40-64 years	118,252	100.0%	117,166	99.1%	789	0.7%	162	0.1%	105	0.1%	22	0.0%	8	0.0%
65+ years	56,267	100.0%	54,972	97.7%	649	1.2%	254	0.5%	287	0.5%	82	0.1%	23	0.0%
Ranitidine, All (0-day washout, 0-day gap)	4,530,789	100.0%	1,911,868	42.2%	610,431	13.5%	372,029	8.2%	595,959	13.2%	432,225	9.5%	608,277	13.4%
<2 years	702,434	100.0%	277,876	39.6%	132,312	18.8%	77,731	11.1%	129,675	18.5%	67,081	9.5%	17,759	2.5%
2-11 years	337,026	100.0%	219,549	65.1%	47,623	14.1%	19,405	5.8%	28,038	8.3%	12,634	3.7%	9,777	2.9%
12-17 years	179,377	100.0%	103,328	57.6%	27,484	15.3%	12,545	7.0%	20,090	11.2%	9,066	5.1%	6,864	3.8%
18-39 years	908,207	100.0%	489,947	53.9%	135,623	14.9%	65,939	7.3%	101,839	11.2%	56,765	6.3%	58,094	6.4%
40-64 years	1,490,830	100.0%	563,722	37.8%	178,223	12.0%	115,180	7.7%	194,716	13.1%	164,568	11.0%	274,421	18.4%
65+ years	912,915	100.0%	257,446	28.2%	89,166	9.8%	81,229	8.9%	121,601	13.3%	122,111	13.4%	241,362	26.4%
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	2,333,213	100.0%	959,133	41.1%	316,023	13.5%	137,086	5.9%	370,235	15.9%	225,015	9.6%	325,721	14.0%
<2 years	29,905	100.0%	12,873	43.0%	5,211	17.4%	3,114	10.4%	4,770	16.0%	2,897	9.7%	1,040	3.5%
2-11 years	41,134	100.0%	27,764	67.5%	5,476	13.3%	2,151	5.2%	2,835	6.9%	1,581	3.8%	1,327	3.2%
12-17 years	62,600	100.0%	41,704	66.6%	9,351	14.9%	2,951	4.7%	4,823	7.7%	2,237	3.6%	1,534	2.5%
18-39 years	609,422	100.0%	316,615	52.0%	97,217	16.0%	29,394	4.8%	99,770	16.4%	37,448	6.1%	28,978	4.8%
40-64 years	954,089	100.0%	356,263	37.3%	130,217	13.6%	56,067	5.9%	162,946	17.1%	101,085	10.6%	147,511	15.5%
65+ years	636,063	100.0%	203,914	32.1%	68,551	10.8%	43,409	6.8%	95,091	14.9%	79,767	12.5%	145,331	22.8%

Table 2c. Distribution of Patients' Cumulative Exposure Durationin the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, All Episodes, in Days, by Age Group

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	360,750	100.0%	358,379	99.3%	1,297	0.4%	414	0.1%	447	0.1%	145	0.0%	68	0.0%
<2 years	797	100.0%	772	96.9%	10	1.3%	8	1.0%	6	0.8%	1	0.1%	0	0.0%
2-11 years	4,201	100.0%	4,145	98.7%	23	0.5%	9	0.2%	16	0.4%	6	0.1%	2	0.0%
12-17 years	10,407	100.0%	10,387	99.8%	7	0.1%	4	0.0%	5	0.0%	3	0.0%	1	0.0%
18-39 years	115,774	100.0%	115,551	99.8%	119	0.1%	47	0.0%	33	0.0%	16	0.0%	8	0.0%
40-64 years	190,439	100.0%	189,312	99.4%	724	0.4%	167	0.1%	155	0.1%	52	0.0%	29	0.0%
65+ years	39,132	100.0%	38,212	97.6%	414	1.1%	179	0.5%	232	0.6%	67	0.2%	28	0.1%
Famotidine, All (0-day washout, 0-day gap)	2,660,511	100.0%	1,277,707	48.0%	322,104	12.1%	138,096	5.2%	371,569	14.0%	225,214	8.5%	325,821	12.2%
<2 years	30,565	100.0%	13,480	44.1%	5,235	17.1%	3,118	10.2%	4,791	15.7%	2,898	9.5%	1,043	3.4%
2-11 years	44,914	100.0%	31,423	70.0%	5,553	12.4%	2,170	4.8%	2,853	6.4%	1,588	3.5%	1,327	3.0%
12-17 years	72,113	100.0%	50,996	70.7%	9,505	13.2%	2,982	4.1%	4,846	6.7%	2,246	3.1%	1,538	2.1%
18-39 years	714,604	100.0%	419,547	58.7%	98,941	13.8%	29,640	4.1%	100,011	14.0%	37,472	5.2%	28,993	4.1%
40-64 years	1,128,751	100.0%	526,506	46.6%	133,300	11.8%	56,570	5.0%	163,614	14.5%	101,190	9.0%	147,571	13.1%
65+ years	669,564	100.0%	235,755	35.2%	69,570	10.4%	43,616	6.5%	95,454	14.3%	79,820	11.9%	145,349	21.7%
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,778,587	100.0%	1,205,298	43.4%	318,804	11.5%	241,978	8.7%	376,906	13.6%	259,679	9.3%	375,922	13.5%
<2 years	86,058	100.0%	48,401	56.2%	11,337	13.2%	7,463	8.7%	10,926	12.7%	5,098	5.9%	2,833	3.3%
2-11 years	289,976	100.0%	187,136	64.5%	36,251	12.5%	18,553	6.4%	27,440	9.5%	11,604	4.0%	8,992	3.1%
12-17 years	148,184	100.0%	84,049	56.7%	19,692	13.3%	11,107	7.5%	18,639	12.6%	8,383	5.7%	6,314	4.3%
18-39 years	645,196	100.0%	345,146	53.5%	82,539	12.8%	51,045	7.9%	80,950	12.5%	43,126	6.7%	42,390	6.6%
40-64 years	998,766	100.0%	370,161	37.1%	110,914	11.1%	88,435	8.9%	147,527	14.8%	111,810	11.2%	169,919	17.0%
65+ years	610,407	100.0%	170,405	27.9%	58,071	9.5%	65,375	10.7%	91,424	15.0%	79,658	13.0%	145,474	23.8%
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	181,857	100.0%	135,536	74.5%	15,441	8.5%	13,213	7.3%	13,908	7.6%	2,955	1.6%	804	0.4%
<2 years	657	100.0%	621	94.5%	11	1.7%	8	1.2%	7	1.1%	9	1.4%	1	0.2%
2-11 years	3,995	100.0%	3,857	96.5%	37	0.9%	29	0.7%	36	0.9%	23	0.6%	13	0.3%
12-17 years	5,239	100.0%	5,148	98.3%	39	0.7%	17	0.3%	19	0.4%	8	0.2%	8	0.2%
18-39 years	36,299	100.0%	33,539	92.4%	1,021	2.8%	824	2.3%	755	2.1%	124	0.3%	36	0.1%
40-64 years	90,690	100.0%	64,425	71.0%	8,641	9.5%	7,851	8.7%	7,749	8.5%	1,563	1.7%	461	0.5%

Table 2c. Distribution of Patients' Cumulative Exposure Durationin the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, All Episodes, in Days, by Age Group

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
65+ years	44,977	100.0%	27,946	62.1%	5,692	12.7%	4,484	10.0%	5,342	11.9%	1,228	2.7%	285	0.6%

Table 2c. Distribution of Patients' Cumulative Exposure Durationin the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, All Episodes, in Days, by Age Group

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Ranitidine, All (183-day washout, 30-day gap)	2,943,890	100.0%	1,318,768	44.8%	337,064	11.4%	255,495	8.7%	392,083	13.3%	263,201	8.9%	377,279	12.8%
<2 years	86,662	100.0%	48,901	56.4%	11,381	13.1%	7,485	8.6%	10,947	12.6%	5,111	5.9%	2,837	3.3%
2-11 years	293,443	100.0%	190,198	64.8%	36,447	12.4%	18,627	6.3%	27,511	9.4%	11,641	4.0%	9,019	3.1%
12-17 years	152,868	100.0%	88,242	57.7%	19,979	13.1%	11,195	7.3%	18,714	12.2%	8,409	5.5%	6,329	4.1%
18-39 years	677,126	100.0%	372,414	55.0%	84,664	12.5%	52,152	7.7%	82,074	12.1%	43,331	6.4%	42,491	6.3%
40-64 years	1,082,259	100.0%	425,161	39.3%	120,568	11.1%	96,348	8.9%	155,797	14.4%	113,684	10.5%	170,701	15.8%
65+ years	651,532	100.0%	193,852	29.8%	64,025	9.8%	69,688	10.7%	97,040	14.9%	81,025	12.4%	145,902	22.4%
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,855,324	100.0%	769,058	41.5%	229,793	12.4%	110,887	6.0%	313,105	16.9%	176,426	9.5%	256,055	13.8%
<2 years	4,769	100.0%	2,907	61.0%	552	11.6%	334	7.0%	525	11.0%	269	5.6%	182	3.8%
2-11 years	33,246	100.0%	22,903	68.9%	3,743	11.3%	1,863	5.6%	2,459	7.4%	1,225	3.7%	1,053	3.2%
12-17 years	53,079	100.0%	35,610	67.1%	7,167	13.5%	2,616	4.9%	4,426	8.3%	1,902	3.6%	1,358	2.6%
18-39 years	482,399	100.0%	247,608	51.3%	70,753	14.7%	24,368	5.1%	84,431	17.5%	30,959	6.4%	24,280	5.0%
40-64 years	772,232	100.0%	290,549	37.6%	96,875	12.5%	45,794	5.9%	140,674	18.2%	81,152	10.5%	117,188	15.2%
65+ years	509,599	100.0%	169,481	33.3%	50,703	9.9%	35,912	7.0%	80,590	15.8%	60,919	12.0%	111,994	22.0%
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	288,232	100.0%	254,512	88.3%	11,193	3.9%	10,636	3.7%	9,349	3.2%	1,933	0.7%	609	0.2%
<2 years	341	100.0%	323	94.7%	2	0.6%	5	1.5%	5	1.5%	4	1.2%	2	0.6%
2-11 years	3,363	100.0%	3,288	97.8%	26	0.8%	13	0.4%	14	0.4%	12	0.4%	10	0.3%
12-17 years	8,677	100.0%	8,602	99.1%	30	0.3%	12	0.1%	18	0.2%	10	0.1%	5	0.1%
18-39 years	89,040	100.0%	86,182	96.8%	1,132	1.3%	905	1.0%	649	0.7%	123	0.1%	49	0.1%
40-64 years	154,622	100.0%	130,862	84.6%	7,622	4.9%	7,786	5.0%	6,617	4.3%	1,317	0.9%	418	0.3%
65+ years	32,189	100.0%	25,255	78.5%	2,381	7.4%	1,915	5.9%	2,046	6.4%	467	1.5%	125	0.4%
Famotidine, All (183-day washout, 30-day gap)	2,128,162	100.0%	1,002,378	47.1%	244,580	11.5%	121,888	5.7%	323,424	15.2%	178,832	8.4%	257,060	12.1%
<2 years	5,105	100.0%	3,215	63.0%	562	11.0%	338	6.6%	531	10.4%	274	5.4%	185	3.6%
2-11 years	36,468	100.0%	25,979	71.2%	3,819	10.5%	1,887	5.2%	2,480	6.8%	1,240	3.4%	1,063	2.9%
12-17 years	61,340	100.0%	43,586	71.1%	7,341	12.0%	2,647	4.3%	4,468	7.3%	1,927	3.1%	1,371	2.2%
18-39 years	566,529	100.0%	326,960	57.7%	73,276	12.9%	25,464	4.5%	85,306	15.1%	31,140	5.5%	24,383	4.3%
40-64 years	919,552	100.0%	411,266	44.7%	106,098	11.5%	53,764	5.8%	147,834	16.1%	82,767	9.0%	117,823	12.8%

Table 2c. Distribution of Patients' Cumulative Exposure Durationin the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, All Episodes, in Days, by Age Group

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
65+ years	539,168	100.0%	191,372	35.5%	53,484	9.9%	37,788	7.0%	82,805	15.4%	61,484	11.4%	112,235	20.8%

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

Table 3a. Descriptive Statistics of Patients' Cumulative Exposure Durationin the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, All Episodes, in Days, Overall

Exposure	Form	Design	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine	Oral	0-day washout, 0-day gap	4,330,042	217.12	462.04	1	30	60	180	7,057
Ranitidine	Inj/IV[2]	0-day washout, 0-day gap	236,136	4.00	13.46	1	1	1	4	2,341
Ranitidine	Any	0-day washout, 0-day gap	4,530,789	207.70	453.82	1	30	60	180	7,057
Famotidine	Oral	0-day washout, 0-day gap	2,333,213	217.14	474.10	1	30	60	180	6,797
Famotidine	Inj/IV	0-day washout, 0-day gap	360,750	2.69	15.04	1	1	1	1	3,258
Famotidine	Any	0-day washout, 0-day gap	2,660,511	190.78	449.57	1	15	45	134	6,797
Ranitidine	Oral	183-day washout, 30-day gap	2,778,587	200.08	429.14	1	30	60	165	6,806
Ranitidine	Inj/IV	183-day washout, 30-day gap	181,857	27.27	61.46	1	1	1	34	2,743
Ranitidine	Any	183-day washout, 30-day gap	2,943,890	190.74	419.18	1	30	59	150	6,806
Famotidine	Oral	183-day washout, 30-day gap	1,855,324	216.53	482.60	1	30	60	161	6,255
Famotidine	Inj/IV	183-day washout, 30-day gap	288,232	13.11	44.47	1	1	1	1	2,825
Famotidine	Any	183-day washout, 30-day gap	2,128,162	190.82	456.08	1	20	50	130	6,255

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

[2]Injection/Intravenous

Table 3b. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, All Episodes, in Days, by Sex

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	4,330,042	217.12	462.04	1	30	60	180	7,057
Female	2,573,465	215.21	449.85	1	30	60	180	7,057
Male	1,756,421	219.92	479.33	1	30	60	180	7,055
Other	156	150.21	223.91	2	30	60	150	1,170
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	236,136	4	13.46	1	1	1	4	2,341
Female	152,842	4.14	13.97	1	1	1	4	2,341
Male	83,274	3.75	12.48	1	1	1	3	942
Other	20	6.95	5.21	1	3	6	12	18
Ranitidine, All (0-day washout, 0-day gap)	4,530,789	207.7	453.82	1	30	60	180	7,057
Female	2,702,337	205.17	441.31	1	30	60	180	7,057
Male	1,828,279	211.44	471.7	1	30	60	180	7,055
Other	173	136.25	216.77	1	30	50	123	1,170
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	2,333,213	217.14	474.1	1	30	60	180	6,797
Female	1,419,784	210.69	456.87	1	30	60	171	6,667
Male	913,290	227.16	499.55	1	30	60	180	6,797
Other	139	223.08	450.38	3	30	90	165	3,550
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	360,750	2.69	15.04	1	1	1	1	3,258
Female	235,966	2.85	16.44	1	1	1	2	3,258
Male	124,779	2.37	11.95	1	1	1	1	1,349
Other	5	2.4	1.95	1	1	1	4	5
Famotidine, All (0-day washout, 0-day gap)	2,660,511	190.78	449.57	1	15	45	134	6,797
Female	1,633,603	183.52	431.7	1	15	42	130	6,667
Male	1,026,765	202.34	476.39	1	20	50	150	6,797
Other	143	216.92	445.48	1	30	90	153	3,550
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,778,587	200.08	429.14	1	30	60	165	6,806
Female	1,719,259	196.96	414.39	1	30	60	166	6,797
Male	1,059,222	205.15	452.04	1	30	60	162	6,806
Other	106	157.37	236.13	7	30	60	166	1,176
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	181,857	27.27	61.46	1	1	1	34	2,743
Female	117,194	29.78	63.53	1	1	1	43	2,743
Male	64,646	22.72	57.23	1	1	1	22	2,341
Other	17	70.06	56.97	1	19	79	99	211

Table 3b. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, All Episodes, in Days, by Sex

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, All (183-day washout, 30-day gap)	2,943,890	190.74	419.18	1	30	59	150	6,806
Female	1,824,863	187.71	404.52	1	30	60	151	6,797
Male	1,118,905	195.7	442.01	1	30	50	150	6,806
Other	122	146.49	222.86	1	30	62	150	1,176
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,855,324	216.53	482.6	1	30	60	161	6,255
Female	1,133,185	210.61	465.04	1	30	60	160	6,246
Male	722,014	225.83	508.81	1	30	58	164	6,255
Other	125	223.76	454.91	3	30	91	180	3,550
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	288,232	13.11	44.47	1	1	1	1	2,825
Female	187,987	14.95	46.94	1	1	1	2	2,825
Male	100,242	9.67	39.21	1	1	1	1	2,333
Other	3	34.33	36.91	1	1	28	74	74
Famotidine, All (183-day washout, 30-day gap)	2,128,162	190.82	456.08	1	20	50	130	6,255
Female	1,310,961	184.47	437.94	1	20	50	130	6,246
Male	817,073	201	483.58	1	21	50	131	6,255
Other	128	219.32	450.45	1	30	90	180	3,550

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

Table 3c. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, All Episodes, in Days, by Age Group

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	4,330,042	217.12	462.04	1	30	60	180	7,057
<2 years	701,599	94.78	125.89	1	30	60	120	5,974
2-11 years	333,389	71.29	166.68	1	24	30	60	5,919
12-17 years	174,101	87.84	188.55	1	30	30	90	6,639
18-39 years	868,090	121.61	289.36	1	30	30	90	6,937
40-64 years	1,387,629	287.91	562.73	1	30	90	270	7,057
65+ years	865,234	380.8	614.9	1	36	120	440	7,028
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	236,136	4	13.46	1	1	1	4	2,341
<2 years	1,377	6.73	34.85	1	1	1	2	785
2-11 years	5,121	3.01	18.66	1	1	1	1	734
12-17 years	6,456	1.98	15.08	1	1	1	1	942
18-39 years	48,663	1.93	4.36	1	1	1	1	213
40-64 years	118,252	3.96	11.68	1	1	1	4	2,341
65+ years	56,267	6.14	19.01	1	1	2	6	1,143
Ranitidine, All (0-day washout, 0-day gap)	4,530,789	207.7	453.82	1	30	60	180	7,057
<2 years	702,434	94.68	125.86	1	30	60	120	5,974
2-11 years	337,026	70.57	165.96	1	24	30	60	5,919
12-17 years	179,377	85.35	186.33	1	30	30	90	6,639
18-39 years	908,207	116.37	284.01	1	30	30	90	6,937
40-64 years	1,490,830	268.31	547.68	1	30	63	243	7,057
65+ years	912,915	361.2	604.4	1	30	120	400	7,028
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	2,333,213	217.14	474.1	1	30	60	180	6,797
<2 years	29,905	98.18	144.94	1	30	60	120	5,367
2-11 years	41,134	70.11	178.71	1	15	30	60	6,797
12-17 years	62,600	63.58	151.04	1	15	30	59	5,266
18-39 years	609,422	102.38	252.69	1	30	30	100	6,667
40-64 years	954,089	242.72	520.19	1	30	60	200	6,555
65+ years	636,063	318.93	569.03	1	30	97	330	6,378
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	360,750	2.69	15.04	1	1	1	1	3,258
<2 years	797	4.67	16.48	1	1	1	2	200
2-11 years	4,201	2.92	18.04	1	1	1	1	684
12-17 years	10,407	1.44	7.9	1	1	1	1	506
18-39 years	115,774	1.58	8.21	1	1	1	1	1,349
40-64 years	190,439	2.85	12.52	1	1	1	2	2,205
65+ years	39,132	5.41	32.48	1	1	1	3	3,258

Table 3c. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, All Episodes, in Days, by Age Group

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, All (0-day washout, 0-day gap)	2,660,511	190.78	449.57	1	15	45	134	6,797
<2 years	30,565	96.32	144.94	1	30	56	120	5,367
2-11 years	44,914	64.4	171.7	1	12	30	50	6,797
12-17 years	72,113	55.48	142.45	1	10	30	50	5,266
18-39 years	714,604	87.57	236.11	1	10	30	90	6,667
40-64 years	1,128,751	205.66	486.09	1	15	50	150	6,555
65+ years	669,564	303.22	558.85	1	30	90	300	6,378
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,778,587	200.08	429.14	1	30	60	165	6,806
<2 years	86,058	84.26	177.45	1	30	30	86	6,164
2-11 years	289,976	73.17	172.07	1	24	30	60	5,937
12-17 years	148,184	90.14	191.3	1	30	30	90	5,375
18-39 years	645,196	118.27	280.43	1	30	30	96	6,706
40-64 years	998,766	245.1	497.15	1	30	70	218	6,806
65+ years	610,407	316.18	535.77	1	30	100	349	6,730
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	181,857	27.27	61.46	1	1	1	34	2,743
<2 years	657	9.7	53.28	1	1	1	1	1,054
2-11 years	3,995	7.36	52.78	1	1	1	1	2,101
12-17 years	5,239	3.68	28.64	1	1	1	1	1,183
18-39 years	36,299	8.46	32.59	1	1	1	1	1,283
40-64 years	90,690	30.46	64.61	1	1	1	43	2,743
65+ years	44,977	40.8	70.86	1	1	8	62	2,341
Ranitidine, All (183-day washout, 30-day gap)	2,943,890	190.74	419.18	1	30	59	150	6,806
<2 years	86,662	83.85	177.34	1	30	30	85	6,164
2-11 years	293,443	72.5	171.46	1	24	30	60	5,937
12-17 years	152,868	87.64	189.02	1	30	30	89	5,375
18-39 years	677,126	113.32	274.94	1	30	30	90	6,706
40-64 years	1,082,259	229.05	481.44	1	30	60	200	6,806
65+ years	651,532	299.25	523.25	1	30	90	315	6,730
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,855,324	216.53	482.6	1	30	60	161	6,255
<2 years	4,769	82.6	176.94	1	25	30	71	4,736
2-11 years	33,246	68.43	175.33	1	15	30	54	4,838
12-17 years	53,079	63.95	155.29	1	15	30	50	5,455
18-39 years	482,399	106.34	265.4	1	30	30	100	6,255
40-64 years	772,232	241.83	529.64	1	30	60	197	6,178
65+ years	509,599	309.32	571.2	1	30	90	300	6,246

Table 3c. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, All Episodes, in Days, by Age Group

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	288,232	13.11	44.47	1	1	1	1	2,825
<2 years	341	11.17	51.77	1	1	1	1	524
2-11 years	3,363	6.08	60.65	1	1	1	1	2,333
12-17 years	8,677	2.47	27.72	1	1	1	1	2,199
18-39 years	89,040	4.33	24.36	1	1	1	1	2,259
40-64 years	154,622	16.69	49	1	1	1	2	2,568
65+ years	32,189	23.84	59.09	1	1	1	22	2,825
Famotidine, All (183-day washout, 30-day gap)	2,128,162	190.82	456.08	1	20	50	130	6,255
<2 years	5,105	78.77	177.86	1	25	30	64	4,736
2-11 years	36,468	63	168.87	1	10	30	50	4,838
12-17 years	61,340	55.99	146.86	1	10	30	50	5,455
18-39 years	566,529	91.43	247.84	1	13	30	90	6,255
40-64 years	919,552	206.22	492.8	1	22	50	150	6,178
65+ years	539,168	294.04	559.37	1	30	90	281	6,246

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

Table 4a. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, Overall

			Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposure	**Form**	**Design**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine	Oral	0-day washout, 0-day gap	13,432,147	100.0%	8,065,711	60.0%	1,991,819	14.8%	1,447,153	10.8%	1,217,453	9.1%	446,025	3.3%	263,986	2.0%
Ranitidine	Inj/IV[2]	0-day washout, 0-day gap	781,452	100.0%	780,324	99.9%	600	0.1%	310	0.0%	186	0.0%	28	0.0%	4	0.0%
Ranitidine	Any	0-day washout, 0-day gap	14,192,176	100.0%	8,823,694	62.2%	1,993,265	14.0%	1,447,445	10.2%	1,217,716	8.6%	446,059	3.1%	263,997	1.9%
Famotidine	Oral	0-day washout, 0-day gap	6,398,339	100.0%	2,960,236	46.3%	1,204,555	18.8%	550,361	8.6%	1,258,104	19.7%	280,595	4.4%	144,488	2.3%
Famotidine	Inj/IV	0-day washout, 0-day gap	767,649	100.0%	766,237	99.8%	765	0.1%	345	0.0%	229	0.0%	58	0.0%	15	0.0%
Famotidine	Any	0-day washout, 0-day gap	7,145,037	100.0%	3,704,335	51.8%	1,206,440	16.9%	550,671	7.7%	1,258,413	17.6%	280,664	3.9%	144,514	2.0%
Ranitidine	Oral	183-day washout, 30-day gap	5,023,316	100.0%	2,528,659	50.3%	551,917	11.0%	646,500	12.9%	673,892	13.4%	334,147	6.7%	288,201	5.7%
Ranitidine	Inj/IV	183-day washout, 30-day gap	218,692	100.0%	167,655	76.7%	19,888	9.1%	14,489	6.6%	14,415	6.6%	1,889	0.9%	356	0.2%
Ranitidine	Any	183-day washout, 30-day gap	5,242,515	100.0%	2,692,465	51.4%	573,715	10.9%	661,687	12.6%	689,277	13.1%	336,489	6.4%	288,882	5.5%
Famotidine	Oral	183-day washout, 30-day gap	3,348,720	100.0%	1,300,497	38.8%	580,956	17.3%	261,385	7.8%	779,912	23.3%	230,643	6.9%	195,327	5.8%
Famotidine	Inj/IV	183-day washout, 30-day gap	325,318	100.0%	288,562	88.7%	13,832	4.3%	11,597	3.6%	9,715	3.0%	1,307	0.4%	305	0.1%
Famotidine	Any	183-day washout, 30-day gap	3,671,091	100.0%	1,581,824	43.1%	596,956	16.3%	273,548	7.5%	790,540	21.5%	232,307	6.3%	195,916	5.3%

[1]Distribution of all episode durations represents each episode's total episode length across all patients

[2]Injection/Intravenous

Table 4b. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Sex

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid														
(0-day washout, 0-day gap)	13,432,147	100.0%	8,065,711	60.0%	1,991,819	14.8%	1,447,153	10.8%	1,217,453	9.1%	446,025	3.3%	263,986	2.0%
Female	8,085,936	100.0%	4,921,224	60.9%	1,173,800	14.5%	867,567	10.7%	713,293	8.8%	258,132	3.2%	151,920	1.9%
Male	5,345,865	100.0%	3,144,296	58.8%	817,965	15.3%	579,545	10.8%	504,121	9.4%	187,877	3.5%	112,061	2.1%
Other	346	100.0%	191	55.2%	54	15.6%	41	11.8%	39	11.3%	16	4.6%	5	1.4%
Ranitidine, Injection/intravenous														
(0-day washout, 0-day gap)	781,452	100.0%	780,324	99.9%	600	0.1%	310	0.0%	186	0.0%	28	0.0%	4	0.0%
Female	532,516	100.0%	531,792	99.9%	360	0.1%	212	0.0%	130	0.0%	20	0.0%	2	0.0%
Male	248,800	100.0%	248,396	99.8%	240	0.1%	98	0.0%	56	0.0%	8	0.0%	2	0.0%
Other	136	100.0%	136	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Ranitidine, All														
(0-day washout, 0-day gap)	14,192,176	100.0%	8,823,694	62.2%	1,993,265	14.0%	1,447,445	10.2%	1,217,716	8.6%	446,059	3.1%	263,997	1.9%
Female	8,604,815	100.0%	5,438,767	63.2%	1,174,725	13.7%	867,770	10.1%	713,467	8.3%	258,160	3.0%	151,926	1.8%
Male	5,586,880	100.0%	3,384,601	60.6%	818,486	14.7%	579,634	10.4%	504,210	9.0%	187,883	3.4%	112,066	2.0%
Other	481	100.0%	326	67.8%	54	11.2%	41	8.5%	39	8.1%	16	3.3%	5	1.0%
Famotidine, Oral solid/liquid														
(0-day washout, 0-day gap)	6,398,339	100.0%	2,960,236	46.3%	1,204,555	18.8%	550,361	8.6%	1,258,104	19.7%	280,595	4.4%	144,488	2.3%
Female	3,875,525	100.0%	1,832,270	47.3%	717,601	18.5%	327,313	8.4%	752,054	19.4%	163,804	4.2%	82,483	2.1%
Male	2,522,436	100.0%	1,127,848	44.7%	486,836	19.3%	223,025	8.8%	505,956	20.1%	116,770	4.6%	62,001	2.5%
Other	378	100.0%	118	31.2%	118	31.2%	23	6.1%	94	24.9%	21	5.6%	4	1.1%
Famotidine, Injection/intravenous														
(0-day washout, 0-day gap)	767,649	100.0%	766,237	99.8%	765	0.1%	345	0.0%	229	0.0%	58	0.0%	15	0.0%
Female	539,363	100.0%	538,409	99.8%	504	0.1%	237	0.0%	160	0.0%	42	0.0%	11	0.0%
Male	228,274	100.0%	227,816	99.8%	261	0.1%	108	0.0%	69	0.0%	16	0.0%	4	0.0%
Other	12	100.0%	12	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Famotidine, All														
(0-day washout, 0-day gap)	7,145,037	100.0%	3,704,335	51.8%	1,206,440	16.9%	550,671	7.7%	1,258,413	17.6%	280,664	3.9%	144,514	2.0%
Female	4,401,418	100.0%	2,356,408	53.5%	718,859	16.3%	327,517	7.4%	752,280	17.1%	163,853	3.7%	82,501	1.9%
Male	2,743,230	100.0%	1,347,798	49.1%	487,463	17.8%	223,131	8.1%	506,039	18.4%	116,790	4.3%	62,009	2.3%
Other	389	100.0%	129	33.2%	118	30.3%	23	5.9%	94	24.2%	21	5.4%	4	1.0%
Ranitidine, Oral solid/liquid														
(183-day washout, 30-day gap)	5,023,316	100.0%	2,528,659	50.3%	551,917	11.0%	646,500	12.9%	673,892	13.4%	334,147	6.7%	288,201	5.7%
Female	3,157,951	100.0%	1,609,733	51.0%	338,517	10.7%	410,250	13.0%	420,016	13.3%	206,740	6.5%	172,695	5.5%
Male	1,865,213	100.0%	918,856	49.3%	213,379	11.4%	236,234	12.7%	253,853	13.6%	127,393	6.8%	115,498	6.2%
Other	152	100.0%	70	46.1%	21	13.8%	16	10.5%	23	15.1%	14	9.2%	8	5.3%

Table 4b. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Sex

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Injection/intravenous														
(183-day washout, 30-day gap)	218,692	100.0%	167,655	76.7%	19,888	9.1%	14,489	6.6%	14,415	6.6%	1,889	0.9%	356	0.2%
Female	141,428	100.0%	105,115	74.3%	13,266	9.4%	10,981	7.8%	10,556	7.5%	1,249	0.9%	261	0.2%
Male	77,243	100.0%	62,531	81.0%	6,620	8.6%	3,504	4.5%	3,854	5.0%	639	0.8%	95	0.1%
Other	21	100.0%	9	42.9%	2	9.5%	4	19.0%	5	23.8%	1	4.8%	0	0.0%
Ranitidine, All														
(183-day washout, 30-day gap)	5,242,515	100.0%	2,692,465	51.4%	573,715	10.9%	661,687	12.6%	689,277	13.1%	336,489	6.4%	288,882	5.5%
Female	3,300,037	100.0%	1,712,537	51.9%	353,088	10.7%	421,736	12.8%	431,225	13.1%	208,280	6.3%	173,171	5.2%
Male	1,942,305	100.0%	979,849	50.4%	220,604	11.4%	239,931	12.4%	258,024	13.3%	128,194	6.6%	115,703	6.0%
Other	173	100.0%	79	45.7%	23	13.3%	20	11.6%	28	16.2%	15	8.7%	8	4.6%
Famotidine, Oral solid/liquid														
(183-day washout, 30-day gap)	3,348,720	100.0%	1,300,497	38.8%	580,956	17.3%	261,385	7.8%	779,912	23.3%	230,643	6.9%	195,327	5.8%
Female	2,069,612	100.0%	819,752	39.6%	352,234	17.0%	162,804	7.9%	481,533	23.3%	139,780	6.8%	113,509	5.5%
Male	1,278,880	100.0%	480,674	37.6%	228,670	17.9%	98,575	7.7%	298,310	23.3%	90,846	7.1%	81,805	6.4%
Other	228	100.0%	71	31.1%	52	22.8%	6	2.6%	69	30.3%	17	7.5%	13	5.7%
Famotidine, Injection/intravenous														
(183-day washout, 30-day gap)	325,318	100.0%	288,562	88.7%	13,832	4.3%	11,597	3.6%	9,715	3.0%	1,307	0.4%	305	0.1%
Female	213,823	100.0%	185,746	86.9%	10,027	4.7%	9,426	4.4%	7,479	3.5%	917	0.4%	228	0.1%
Male	111,492	100.0%	102,814	92.2%	3,805	3.4%	2,170	1.9%	2,236	2.0%	390	0.3%	77	0.1%
Other	3	100.0%	2	66.7%	0	0.0%	1	33.3%	0	0.0%	0	0.0%	0	0.0%
Famotidine, All														
(183-day washout, 30-day gap)	3,671,091	100.0%	1,581,824	43.1%	596,956	16.3%	273,548	7.5%	790,540	21.5%	232,307	6.3%	195,916	5.3%
Female	2,281,899	100.0%	1,001,149	43.9%	363,662	15.9%	172,571	7.6%	489,672	21.5%	140,936	6.2%	113,909	5.0%
Male	1,388,961	100.0%	580,602	41.8%	233,242	16.8%	100,970	7.3%	300,799	21.7%	91,354	6.6%	81,994	5.9%
Other	231	100.0%	73	31.6%	52	22.5%	7	3.0%	69	29.9%	17	7.4%	13	5.6%

[1]Distribution of all episode durations represents each episode's total episode length across all patients

Table 4c. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Age Group

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid														
(0-day washout, 0-day gap)	13,432,147	100.0%	8,065,711	60.0%	1,991,819	14.8%	1,447,153	10.8%	1,217,453	9.1%	446,025	3.3%	263,986	2.0%
<2 years	1,226,485	100.0%	821,598	67.0%	181,756	14.8%	74,868	6.1%	98,353	8.0%	41,389	3.4%	8,521	0.7%
2-11 years	633,611	100.0%	530,013	83.6%	55,838	8.8%	18,103	2.9%	22,258	3.5%	4,864	0.8%	2,535	0.4%
12-17 years	375,668	100.0%	305,182	81.2%	35,662	9.5%	13,125	3.5%	16,802	4.5%	3,351	0.9%	1,546	0.4%
18-39 years	2,164,738	100.0%	1,590,132	73.5%	279,184	12.9%	119,191	5.5%	129,119	6.0%	31,193	1.4%	15,919	0.7%
40-64 years	5,466,271	100.0%	3,166,776	57.9%	871,190	15.9%	601,351	11.0%	528,539	9.7%	183,154	3.4%	115,261	2.1%
65+ years	3,565,374	100.0%	1,652,010	46.3%	568,189	15.9%	620,515	17.4%	422,382	11.8%	182,074	5.1%	120,204	3.4%
Ranitidine, Injection/intravenous														
(0-day washout, 0-day gap)	781,452	100.0%	780,324	99.9%	600	0.1%	310	0.0%	186	0.0%	28	0.0%	4	0.0%
<2 years	4,361	100.0%	4,333	99.4%	16	0.4%	5	0.1%	3	0.1%	4	0.1%	0	0.0%
2-11 years	10,364	100.0%	10,343	99.8%	7	0.1%	5	0.0%	7	0.1%	0	0.0%	2	0.0%
12-17 years	9,420	100.0%	9,399	99.8%	10	0.1%	7	0.1%	3	0.0%	1	0.0%	0	0.0%
18-39 years	86,482	100.0%	86,448	100.0%	20	0.0%	11	0.0%	3	0.0%	0	0.0%	0	0.0%
40-64 years	430,031	100.0%	429,840	100.0%	99	0.0%	48	0.0%	34	0.0%	9	0.0%	1	0.0%
65+ years	240,794	100.0%	239,961	99.7%	448	0.2%	234	0.1%	136	0.1%	14	0.0%	1	0.0%
Ranitidine, All														
(0-day washout, 0-day gap)	14,192,176	100.0%	8,823,694	62.2%	1,993,265	14.0%	1,447,445	10.2%	1,217,716	8.6%	446,059	3.1%	263,997	1.9%
<2 years	1,230,915	100.0%	825,941	67.1%	181,810	14.8%	74,878	6.1%	98,368	8.0%	41,397	3.4%	8,521	0.7%
2-11 years	643,111	100.0%	539,420	83.9%	55,904	8.7%	18,115	2.8%	22,269	3.5%	4,866	0.8%	2,537	0.4%
12-17 years	384,876	100.0%	314,298	81.7%	35,738	9.3%	13,138	3.4%	16,805	4.4%	3,351	0.9%	1,546	0.4%
18-39 years	2,249,156	100.0%	1,674,059	74.4%	279,528	12.4%	119,268	5.3%	129,171	5.7%	31,206	1.4%	15,924	0.7%
40-64 years	5,887,039	100.0%	3,586,736	60.9%	871,646	14.8%	601,545	10.2%	528,653	9.0%	183,179	3.1%	115,280	2.0%
65+ years	3,797,079	100.0%	1,883,240	49.6%	568,639	15.0%	620,501	16.3%	422,450	11.1%	182,060	4.8%	120,189	3.2%
Famotidine, Oral solid/liquid														
(0-day washout, 0-day gap)	6,398,339	100.0%	2,960,236	46.3%	1,204,555	18.8%	550,361	8.6%	1,258,104	19.7%	280,595	4.4%	144,488	2.3%
<2 years	60,984	100.0%	45,046	73.9%	7,950	13.0%	2,867	4.7%	3,137	5.1%	1,549	2.5%	435	0.7%
2-11 years	77,853	100.0%	63,880	82.1%	8,213	10.5%	2,434	3.1%	2,203	2.8%	738	0.9%	385	0.5%
12-17 years	104,922	100.0%	81,770	77.9%	13,566	12.9%	3,386	3.2%	4,923	4.7%	903	0.9%	374	0.4%
18-39 years	1,135,804	100.0%	653,473	57.5%	212,668	18.7%	44,052	3.9%	197,558	17.4%	20,245	1.8%	7,808	0.7%
40-64 years	2,920,522	100.0%	1,286,150	44.0%	599,823	20.5%	230,488	7.9%	619,023	21.2%	124,090	4.2%	60,948	2.1%
65+ years	2,098,254	100.0%	829,917	39.6%	362,335	17.3%	267,134	12.7%	431,260	20.6%	133,070	6.3%	74,538	3.6%

Table 4c. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Age Group

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Famotidine, Injection/intravenous														
(0-day washout, 0-day gap)	767,649	100.0%	766,237	99.8%	765	0.1%	345	0.0%	229	0.0%	58	0.0%	15	0.0%
<2 years	2,836	100.0%	2,834	99.9%	1	0.0%	1	0.0%	0	0.0%	0	0.0%	0	0.0%
2-11 years	9,232	100.0%	9,216	99.8%	8	0.1%	3	0.0%	4	0.0%	1	0.0%	0	0.0%
12-17 years	13,064	100.0%	13,053	99.9%	6	0.0%	0	0.0%	4	0.0%	1	0.0%	0	0.0%
18-39 years	161,393	100.0%	161,267	99.9%	66	0.0%	30	0.0%	23	0.0%	4	0.0%	3	0.0%
40-64 years	470,662	100.0%	470,207	99.9%	252	0.1%	96	0.0%	78	0.0%	23	0.0%	6	0.0%
65+ years	110,462	100.0%	109,660	99.3%	432	0.4%	215	0.2%	120	0.1%	29	0.0%	6	0.0%
Famotidine, All														
(0-day washout, 0-day gap)	7,145,037	100.0%	3,704,335	51.8%	1,206,440	16.9%	550,671	7.7%	1,258,413	17.6%	280,664	3.9%	144,514	2.0%
<2 years	63,787	100.0%	47,812	75.0%	7,969	12.5%	2,876	4.5%	3,140	4.9%	1,552	2.4%	438	0.7%
2-11 years	86,698	100.0%	72,702	83.9%	8,236	9.5%	2,433	2.8%	2,206	2.5%	739	0.9%	382	0.4%
12-17 years	117,602	100.0%	94,362	80.2%	13,629	11.6%	3,394	2.9%	4,938	4.2%	904	0.8%	375	0.3%
18-39 years	1,291,277	100.0%	808,335	62.6%	213,157	16.5%	44,114	3.4%	197,606	15.3%	20,252	1.6%	7,813	0.6%
40-64 years	3,381,574	100.0%	1,745,971	51.6%	600,647	17.8%	230,671	6.8%	619,187	18.3%	124,133	3.7%	60,965	1.8%
65+ years	2,204,099	100.0%	935,153	42.4%	362,802	16.5%	267,183	12.1%	431,336	19.6%	133,084	6.0%	74,541	3.4%
Ranitidine, Oral solid/liquid														
(183-day washout, 30-day gap)	5,023,316	100.0%	2,528,659	50.3%	551,917	11.0%	646,500	12.9%	673,892	13.4%	334,147	6.7%	288,201	5.7%
<2 years	114,897	100.0%	76,209	66.3%	10,328	9.0%	10,087	8.8%	11,729	10.2%	4,526	3.9%	2,018	1.8%
2-11 years	418,474	100.0%	313,319	74.9%	31,034	7.4%	28,947	6.9%	30,354	7.3%	9,480	2.3%	5,340	1.3%
12-17 years	231,919	100.0%	164,961	71.1%	16,906	7.3%	18,731	8.1%	21,027	9.1%	6,609	2.8%	3,685	1.6%
18-39 years	1,052,982	100.0%	658,016	62.5%	104,996	10.0%	101,407	9.6%	117,995	11.2%	43,847	4.2%	26,721	2.5%
40-64 years	2,013,635	100.0%	908,666	45.1%	245,189	12.2%	270,455	13.4%	306,802	15.2%	153,656	7.6%	128,867	6.4%
65+ years	1,191,409	100.0%	407,488	34.2%	143,464	12.0%	216,873	18.2%	185,985	15.6%	116,029	9.7%	121,570	10.2%
Ranitidine, Injection/intravenous														
(183-day washout, 30-day gap)	218,692	100.0%	167,655	76.7%	19,888	9.1%	14,489	6.6%	14,415	6.6%	1,889	0.9%	356	0.2%
<2 years	706	100.0%	664	94.1%	15	2.1%	10	1.4%	9	1.3%	6	0.8%	2	0.3%
2-11 years	4,311	100.0%	4,149	96.2%	51	1.2%	42	1.0%	40	0.9%	19	0.4%	10	0.2%
12-17 years	5,617	100.0%	5,506	98.0%	57	1.0%	23	0.4%	14	0.2%	11	0.2%	6	0.1%
18-39 years	40,133	100.0%	37,192	92.7%	1,222	3.0%	885	2.2%	736	1.8%	78	0.2%	20	0.0%
40-64 years	109,558	100.0%	80,756	73.7%	10,864	9.9%	8,599	7.8%	8,092	7.4%	1,049	1.0%	198	0.2%
65+ years	58,367	100.0%	39,388	67.5%	7,679	13.2%	4,930	8.4%	5,524	9.5%	726	1.2%	120	0.2%

Table 4c. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Age Group

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, All														
(183-day washout, 30-day gap)	5,242,515	100.0%	2,692,465	51.4%	573,715	10.9%	661,687	12.6%	689,277	13.1%	336,489	6.4%	288,882	5.5%
<2 years	115,678	100.0%	76,892	66.5%	10,370	9.0%	10,104	8.7%	11,749	10.2%	4,539	3.9%	2,024	1.7%
2-11 years	422,912	100.0%	317,385	75.0%	31,204	7.4%	29,025	6.9%	30,425	7.2%	9,514	2.2%	5,359	1.3%
12-17 years	237,809	100.0%	170,533	71.7%	17,100	7.2%	18,786	7.9%	21,064	8.9%	6,632	2.8%	3,694	1.6%
18-39 years	1,093,429	100.0%	694,431	63.5%	106,849	9.8%	102,460	9.4%	118,913	10.9%	43,989	4.0%	26,787	2.4%
40-64 years	2,123,309	100.0%	987,496	46.5%	256,778	12.1%	279,443	13.2%	315,397	14.9%	154,962	7.3%	129,233	6.1%
65+ years	1,249,378	100.0%	445,728	35.7%	151,414	12.1%	221,869	17.8%	191,729	15.3%	116,853	9.4%	121,785	9.7%
Famotidine, Oral solid/liquid														
(183-day washout, 30-day gap)	3,348,720	100.0%	1,300,497	38.8%	580,956	17.3%	261,385	7.8%	779,912	23.3%	230,643	6.9%	195,327	5.8%
<2 years	5,835	100.0%	3,867	66.3%	540	9.3%	457	7.8%	564	9.7%	253	4.3%	154	2.6%
2-11 years	43,812	100.0%	32,406	74.0%	3,998	9.1%	2,871	6.6%	2,638	6.0%	1,157	2.6%	742	1.7%
12-17 years	70,086	100.0%	50,396	71.9%	8,330	11.9%	3,813	5.4%	5,169	7.4%	1,534	2.2%	844	1.2%
18-39 years	725,663	100.0%	370,519	51.1%	126,898	17.5%	37,168	5.1%	152,205	21.0%	25,539	3.5%	13,334	1.8%
40-64 years	1,544,752	100.0%	542,978	35.1%	293,330	19.0%	118,438	7.7%	394,830	25.6%	110,293	7.1%	84,883	5.5%
65+ years	958,572	100.0%	300,331	31.3%	147,860	15.4%	98,638	10.3%	224,506	23.4%	91,867	9.6%	95,370	9.9%
Famotidine, Injection/intravenous														
(183-day washout, 30-day gap)	325,318	100.0%	288,562	88.7%	13,832	4.3%	11,597	3.6%	9,715	3.0%	1,307	0.4%	305	0.1%
<2 years	367	100.0%	346	94.3%	3	0.8%	5	1.4%	7	1.9%	4	1.1%	2	0.5%
2-11 years	3,592	100.0%	3,493	97.2%	29	0.8%	26	0.7%	26	0.7%	10	0.3%	8	0.2%
12-17 years	9,235	100.0%	9,145	99.0%	41	0.4%	16	0.2%	20	0.2%	8	0.1%	5	0.1%
18-39 years	96,100	100.0%	93,117	96.9%	1,239	1.3%	957	1.0%	670	0.7%	88	0.1%	29	0.0%
40-64 years	177,574	100.0%	151,696	85.4%	9,456	5.3%	8,431	4.7%	6,893	3.9%	892	0.5%	206	0.1%
65+ years	38,450	100.0%	30,765	80.0%	3,064	8.0%	2,162	5.6%	2,099	5.5%	305	0.8%	55	0.1%
Famotidine, All														
(183-day washout, 30-day gap)	3,671,091	100.0%	1,581,824	43.1%	596,956	16.3%	273,548	7.5%	790,540	21.5%	232,307	6.3%	195,916	5.3%
<2 years	6,221	100.0%	4,217	67.8%	548	8.8%	463	7.4%	578	9.3%	258	4.1%	157	2.5%
2-11 years	47,394	100.0%	35,829	75.6%	4,073	8.6%	2,906	6.1%	2,668	5.6%	1,169	2.5%	749	1.6%
12-17 years	79,286	100.0%	59,360	74.9%	8,456	10.7%	3,847	4.9%	5,212	6.6%	1,556	2.0%	855	1.1%
18-39 years	820,243	100.0%	460,933	56.2%	128,892	15.7%	38,290	4.7%	153,048	18.7%	25,682	3.1%	13,398	1.6%
40-64 years	1,721,334	100.0%	691,470	40.2%	303,804	17.6%	127,209	7.4%	402,219	23.4%	111,395	6.5%	85,237	5.0%
65+ years	996,613	100.0%	330,015	33.1%	151,183	15.2%	100,833	10.1%	226,815	22.8%	92,247	9.3%	95,520	9.6%

[1]Distribution of all episode durations represents each episode's total episode length across all patients

Table 5a. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, Overall

Exposure	Form	Design	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine	Oral	0-day washout, 0-day gap	13,432,147	69.99	137.58	1	30	30	63	7,057
Ranitidine	Inj/IV[2]	0-day washout, 0-day gap	781,452	1.21	3.78	1	1	1	1	1,283
Ranitidine	Any	0-day washout, 0-day gap	14,192,176	66.31	134.75	1	30	30	60	7,057
Famotidine	Oral	0-day washout, 0-day gap	6,398,339	79.18	142.02	1	30	50	100	6,324
Famotidine	Inj/IV	0-day washout, 0-day gap	767,649	1.26	5.14	1	1	1	1	1,148
Famotidine	Any	0-day washout, 0-day gap	7,145,037	71.04	136.51	1	30	30	90	6,324
Ranitidine	Oral	183-day washout, 30-day gap	5,023,316	110.67	239.23	1	30	30	97	6,806
Ranitidine	Inj/IV	183-day washout, 30-day gap	218,692	22.68	46.50	1	1	1	29	2,642
Ranitidine	Any	183-day washout, 30-day gap	5,242,515	107.11	235.11	1	30	30	91	6,806
Famotidine	Oral	183-day washout, 30-day gap	3,348,720	119.97	264.61	1	30	50	100	6,255
Famotidine	Inj/IV	183-day washout, 30-day gap	325,318	11.62	35.02	1	1	1	1	2,825
Famotidine	Any	183-day washout, 30-day gap	3,671,091	110.62	254.86	1	30	50	100	6,255

[1]Distribution of all episode durations represents each episode's total episode length across all patients

[2]Injection/Intravenous

Table 5b. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Sex

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	13,432,147	69.99	137.58	1	30	30	63	7,057
Female	8,085,936	68.49	131.69	1	30	30	60	7,057
Male	5,345,865	72.26	146.01	1	30	30	84	7,055
Other	346	67.73	90.59	2	30	30	90	870
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	781,452	1.21	3.78	1	1	1	1	1,283
Female	532,516	1.19	3.78	1	1	1	1	1,283
Male	248,800	1.25	3.77	1	1	1	1	513
Other	136	1.02	0.15	1	1	1	1	2
Ranitidine, Oral solid/liquid or Injection/intravenous (0-day washout, 0-day gap)	14,192,176	66.31	134.75	1	30	30	60	7,057
Female	8,604,815	64.43	128.67	1	30	30	60	7,057
Male	5,586,880	69.19	143.56	1	30	30	60	7,055
Other	481	49.01	82.45	1	1	30	50	870
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	6,398,339	79.18	142.02	1	30	50	100	6,324
Female	3,875,525	77.19	135.85	1	30	50	100	6,324
Male	2,522,436	82.25	150.96	1	30	50	100	5,964
Other	378	82.03	190.93	1	30	50	100	3,550
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	767,649	1.26	5.14	1	1	1	1	1,148
Female	539,363	1.25	5.12	1	1	1	1	1,148
Male	228,274	1.3	5.18	1	1	1	1	1,026
Other	12	1	0	1	1	1	1	1
Famotidine, Oral solid/liquid or Injection/intravenous (0-day washout, 0-day gap)	7,145,037	71.04	136.51	1	30	30	90	6,324
Female	4,401,418	68.11	129.85	1	30	30	90	6,324
Male	2,743,230	75.73	146.43	1	30	45	90	5,964
Other	389	79.74	188.69	1	30	50	100	3,550
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	5,023,316	110.67	239.23	1	30	30	97	6,806
Female	3,157,951	107.23	227.04	1	30	30	93	6,797
Male	1,865,213	116.5	258.47	1	30	40	100	6,806
Other	152	109.74	171.67	7	30	50	100	1,095
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	218,692	22.68	46.5	1	1	1	29	2,642
Female	141,428	24.68	48.4	1	1	1	36	2,642
Male	77,243	19.02	42.57	1	1	1	22	1,254
Other	21	56.71	52.55	1	8	52	91	211

Table 5b. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Sex

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid or Injection/intravenous (183-day washout, 30-day gap)	5,242,515	107.11	235.11	1	30	30	91	6,806
Female	3,300,037	103.8	223.04	1	30	30	90	6,797
Male	1,942,305	112.74	254.2	1	30	30	97	6,806
Other	173	103.31	162.77	1	30	50	100	1,095
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	3,348,720	119.97	264.61	1	30	50	100	6,255
Female	2,069,612	115.32	249.49	1	30	50	100	6,222
Male	1,278,880	127.5	287.24	1	30	50	100	6,255
Other	228	122.68	284.07	1	30	50	100	3,550
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	325,318	11.62	35.02	1	1	1	1	2,825
Female	213,823	13.14	37.12	1	1	1	1	2,825
Male	111,492	8.69	30.36	1	1	1	1	1,306
Other	3	34.33	36.91	1	1	28	74	74
Famotidine, Oral solid/liquid or Injection/intravenous (183-day washout, 30-day gap)	3,671,091	110.62	254.86	1	30	50	100	6,255
Female	2,281,899	105.98	239.79	1	30	50	100	6,222
Male	1,388,961	118.24	277.69	1	30	50	100	6,255
Other	231	121.53	282.41	1	30	50	100	3,550

[1]Distribution of all episode durations represents each episode's total episode length across all patients

Table 5c. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	13,432,147	69.99	137.58	1	30	30	63	7,057
<2 years	1,226,485	54.22	69.38	1	30	30	60	4,394
2-11 years	633,611	37.51	62	1	30	30	30	5,919
12-17 years	375,668	40.71	62.84	1	30	30	30	6,521
18-39 years	2,164,738	48.77	89.4	1	30	30	50	6,937
40-64 years	5,466,271	73.09	150.59	1	30	30	90	7,057
65+ years	3,565,374	92.41	166.68	1	30	50	90	7,028
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	781,452	1.21	3.78	1	1	1	1	1,283
<2 years	4,361	2.12	10.24	1	1	1	1	351
2-11 years	10,364	1.49	8.95	1	1	1	1	622
12-17 years	9,420	1.36	4.28	1	1	1	1	187
18-39 years	86,482	1.08	1.47	1	1	1	1	124
40-64 years	430,031	1.09	2.75	1	1	1	1	1,283
65+ years	240,794	1.44	5.08	1	1	1	1	380
Ranitidine, All (0-day washout, 0-day gap)	14,192,176	66.31	134.75	1	30	30	60	7,057
<2 years	1,230,915	54.03	69.33	1	30	30	60	4,394
2-11 years	643,111	36.98	61.7	1	29	30	30	5,919
12-17 years	384,876	39.78	62.37	1	30	30	30	6,521
18-39 years	2,249,156	46.99	88.18	1	30	30	40	6,937
40-64 years	5,887,039	67.95	146.3	1	30	30	60	7,057
65+ years	3,797,079	86.84	162.98	1	30	34	90	7,028
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	6,398,339	79.18	142.02	1	30	50	100	6,324
<2 years	60,984	48.14	69.5	1	30	30	32	5,107
2-11 years	77,853	37.04	62.83	1	20	30	30	3,390
12-17 years	104,922	37.93	56.52	1	20	30	30	3,721
18-39 years	1,135,804	54.93	88.54	1	30	30	60	6,324
40-64 years	2,920,522	79.29	144.9	1	30	50	100	6,107
65+ years	2,098,254	96.68	163.67	1	30	50	100	5,849
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	767,649	1.26	5.14	1	1	1	1	1,148
<2 years	2,836	1.31	2.65	1	1	1	1	78
2-11 years	9,232	1.33	4.93	1	1	1	1	300
12-17 years	13,064	1.15	3.52	1	1	1	1	279
18-39 years	161,393	1.14	4.46	1	1	1	1	1,026
40-64 years	470,662	1.15	3.56	1	1	1	1	862
65+ years	110,462	1.92	9.82	1	1	1	1	1,148

Table 5c. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, All (0-day washout, 0-day gap)	7,145,037	71.04	136.51	1	30	30	90	6,324
<2 years	63,787	46.15	68.74	1	30	30	31	5,107
2-11 years	86,698	33.36	60.47	1	14	30	30	3,390
12-17 years	117,602	34.02	54.62	1	14	30	30	3,721
18-39 years	1,291,277	48.46	84.9	1	15	30	50	6,324
40-64 years	3,381,574	68.65	137.32	1	30	30	90	6,107
65+ years	2,204,099	92.11	160.99	1	30	50	100	5,849
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	5,023,316	110.67	239.23	1	30	30	97	6,806
<2 years	114,897	63.11	118.43	1	30	30	60	6,164
2-11 years	418,474	50.71	100.74	1	28	30	31	5,919
12-17 years	231,919	57.6	109.2	1	30	30	60	5,084
18-39 years	1,052,982	72.47	152.33	1	30	30	69	6,650
40-64 years	2,013,635	121.57	258.93	1	30	50	100	6,806
65+ years	1,191,409	161.99	306.75	1	30	80	139	6,730
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	218,692	22.68	46.5	1	1	1	29	2,642
<2 years	706	9.03	39.56	1	1	1	1	503
2-11 years	4,311	6.82	43.19	1	1	1	1	1,658
12-17 years	5,617	3.43	21.62	1	1	1	1	756
18-39 years	40,133	7.65	26.59	1	1	1	1	961
40-64 years	109,558	25.22	49.3	1	1	1	36	2,642
65+ years	58,367	31.44	50.51	1	1	2	44	1,254
Ranitidine, All (183-day washout, 30-day gap)	5,242,515	107.11	235.11	1	30	30	91	6,806
<2 years	115,678	62.82	118.3	1	30	30	60	6,164
2-11 years	422,912	50.3	100.48	1	26	30	30	5,919
12-17 years	237,809	56.34	108.23	1	30	30	60	5,084
18-39 years	1,093,429	70.18	150.13	1	30	30	66	6,650
40-64 years	2,123,309	116.75	253.4	1	30	50	100	6,806
65+ years	1,249,378	156.05	301.05	1	30	70	129	6,730
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	3,348,720	119.97	264.61	1	30	50	100	6,255
<2 years	5,835	67.51	130.29	1	25	30	60	2,684
2-11 years	43,812	51.92	115.41	1	18	30	37	4,385
12-17 years	70,086	48.43	98.63	1	15	30	50	4,466
18-39 years	725,663	70.69	143.67	1	30	30	100	6,255
40-64 years	1,544,752	120.89	268.38	1	30	50	100	6,178
65+ years	958,572	164.44	327.21	1	30	85	120	6,222

Table 5c. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	325,318	11.62	35.02	1	1	1	1	2,825
<2 years	367	10.38	45.15	1	1	1	1	523
2-11 years	3,592	5.69	43.56	1	1	1	1	1,253
12-17 years	9,235	2.32	17.72	1	1	1	1	1,003
18-39 years	96,100	4.01	19.75	1	1	1	1	1,485
40-64 years	177,574	14.53	38.14	1	1	1	1	1,596
65+ years	38,450	19.96	46.16	1	1	1	22	2,825
Famotidine, All (183-day washout, 30-day gap)	3,671,091	110.62	254.86	1	30	50	100	6,255
<2 years	6,221	64.64	131.01	1	25	30	60	2,684
2-11 years	47,394	48.48	111.78	1	14	30	30	4,385
12-17 years	79,286	43.32	94.32	1	10	30	31	4,466
18-39 years	820,243	63.15	137.03	1	15	30	90	6,255
40-64 years	1,721,334	110.17	256.64	1	30	50	100	6,178
65+ years	996,613	159.07	322.31	1	30	71	117	6,222

[1]Distribution of all episode durations represents each episode's total episode length across all patients

Table 6a. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, Overall

			Total Dispensings		1-30		31-60		61-90		91+	
Exposure	**Form**	**Design**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine	Oral	0-day washout, 0-day gap	22,529,944	100.0%	16,598,319	73.7%	1,869,136	8.3%	3,102,369	13.8%	960,120	4.3%
Ranitidine	Inj/IV[1]	0-day washout, 0-day gap	887,030	100.0%	886,874	100.0%	125	0.0%	20	0.0%	11	0.0%
Ranitidine	Any	0-day washout, 0-day gap	23,416,798	100.0%	17,485,026	74.7%	1,869,260	8.0%	3,102,381	13.2%	960,131	4.1%
Famotidine	Oral	0-day washout, 0-day gap	10,045,808	100.0%	5,734,750	57.1%	1,325,618	13.2%	1,232,005	12.3%	1,753,435	17.5%
Famotidine	Inj/IV	0-day washout, 0-day gap	901,750	100.0%	901,667	100.0%	61	0.0%	21	0.0%	1	0.0%
Famotidine	Any	0-day washout, 0-day gap	10,947,309	100.0%	6,636,170	60.6%	1,325,682	12.1%	1,232,021	11.3%	1,753,436	16.0%
Ranitidine	Oral	183-day washout, 30-day gap	12,495,048	100.0%	9,144,791	73.2%	1,028,830	8.2%	1,687,280	13.5%	634,147	5.1%
Ranitidine	Inj/IV	183-day washout, 30-day gap	654,950	100.0%	654,834	100.0%	89	0.0%	16	0.0%	11	0.0%
Ranitidine	Any	183-day washout, 30-day gap	13,184,623	100.0%	9,832,222	74.6%	1,029,331	7.8%	1,688,895	12.8%	634,175	4.8%
Famotidine	Oral	183-day washout, 30-day gap	7,359,176	100.0%	3,913,666	53.2%	1,108,049	15.1%	789,207	10.7%	1,548,254	21.0%
Famotidine	Inj/IV	183-day washout, 30-day gap	687,322	100.0%	687,273	100.0%	44	0.0%	5	0.0%	0	0.0%
Famotidine	Any	183-day washout, 30-day gap	8,075,881	100.0%	4,628,519	57.3%	1,108,404	13.7%	790,562	9.8%	1,548,396	19.2%

[1]Injection/Intravenous

Table 6b. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Sex

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid										
(0-day washout, 0-day gap)	22,529,944	100.0%	16,598,319	73.7%	1,869,136	8.3%	3,102,369	13.8%	960,120	4.3%
Female	13,366,299	100.0%	9,933,236	74.3%	1,063,434	8.0%	1,826,391	13.7%	543,238	4.1%
Male	9,163,113	100.0%	6,664,735	72.7%	805,641	8.8%	1,275,895	13.9%	416,842	4.5%
Other	532	100.0%	348	65.4%	61	11.5%	83	15.6%	40	7.5%
Ranitidine, Injection/intravenous										
(0-day washout, 0-day gap)	887,030	100.0%	886,874	100.0%	125	0.0%	20	0.0%	11	0.0%
Female	599,411	100.0%	599,320	100.0%	66	0.0%	17	0.0%	8	0.0%
Male	287,480	100.0%	287,415	100.0%	59	0.0%	3	0.0%	3	0.0%
Other	139	100.0%	139	100.0%	0	0.0%	0	0.0%	0	0.0%
Ranitidine, All										
(0-day washout, 0-day gap)	23,416,798	100.0%	17,485,026	74.7%	1,869,260	8.0%	3,102,381	13.2%	960,131	4.1%
Female	13,965,611	100.0%	10,532,462	75.4%	1,063,500	7.6%	1,826,403	13.1%	543,246	3.9%
Male	9,450,516	100.0%	6,952,077	73.6%	805,699	8.5%	1,275,895	13.5%	416,845	4.4%
Other	671	100.0%	487	72.6%	61	9.1%	83	12.4%	40	6.0%
Famotidine, Oral solid/liquid										
(0-day washout, 0-day gap)	10,045,808	100.0%	5,734,750	57.1%	1,325,618	13.2%	1,232,005	12.3%	1,753,435	17.5%
Female	6,002,633	100.0%	3,485,708	58.1%	778,422	13.0%	711,900	11.9%	1,026,603	17.1%
Male	4,042,628	100.0%	2,248,830	55.6%	547,039	13.5%	520,072	12.9%	726,687	18.0%
Other	547	100.0%	212	38.8%	157	28.7%	33	6.0%	145	26.5%
Famotidine, Injection/intravenous										
(0-day washout, 0-day gap)	901,750	100.0%	901,667	100.0%	61	0.0%	21	0.0%	1	0.0%
Female	631,968	100.0%	631,916	100.0%	32	0.0%	19	0.0%	1	0.0%
Male	269,770	100.0%	269,739	100.0%	29	0.0%	2	0.0%	0	0.0%
Other	12	100.0%	12	100.0%	0	0.0%	0	0.0%	0	0.0%
Famotidine, All										
(0-day washout, 0-day gap)	10,947,309	100.0%	6,636,170	60.6%	1,325,682	12.1%	1,232,021	11.3%	1,753,436	16.0%
Female	6,634,432	100.0%	4,117,457	62.1%	778,455	11.7%	711,916	10.7%	1,026,604	15.5%
Male	4,312,318	100.0%	2,518,489	58.4%	547,070	12.7%	520,072	12.1%	726,687	16.9%
Other	559	100.0%	224	40.1%	157	28.1%	33	5.9%	145	25.9%

Table 6b. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Sex

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid										
(183-day washout, 30-day gap)	12,495,048	100.0%	9,144,791	73.2%	1,028,830	8.2%	1,687,280	13.5%	634,147	5.1%
Female	7,683,131	100.0%	5,692,080	74.1%	602,412	7.8%	1,019,740	13.3%	368,899	4.8%
Male	4,811,584	100.0%	3,452,508	71.8%	426,385	8.9%	667,476	13.9%	265,215	5.5%
Other	333	100.0%	203	61.0%	33	9.9%	64	19.2%	33	9.9%
Ranitidine, Injection/intravenous										
(183-day washout, 30-day gap)	654,950	100.0%	654,834	100.0%	89	0.0%	16	0.0%	11	0.0%
Female	445,204	100.0%	445,132	100.0%	51	0.0%	13	0.0%	8	0.0%
Male	209,623	100.0%	209,579	100.0%	38	0.0%	3	0.0%	3	0.0%
Other	123	100.0%	123	100.0%	0	0.0%	0	0.0%	0	0.0%
Ranitidine, All										
(183-day washout, 30-day gap)	13,184,623	100.0%	9,832,222	74.6%	1,029,331	7.8%	1,688,895	12.8%	634,175	4.8%
Female	8,151,137	100.0%	6,158,688	75.6%	602,728	7.4%	1,020,807	12.5%	368,914	4.5%
Male	5,033,030	100.0%	3,673,208	73.0%	426,570	8.5%	668,024	13.3%	265,228	5.3%
Other	456	100.0%	326	71.5%	33	7.2%	64	14.0%	33	7.2%
Famotidine, Oral solid/liquid										
(183-day washout, 30-day gap)	7,359,176	100.0%	3,913,666	53.2%	1,108,049	15.1%	789,207	10.7%	1,548,254	21.0%
Female	4,422,808	100.0%	2,399,272	54.2%	651,404	14.7%	461,698	10.4%	910,434	20.6%
Male	2,935,893	100.0%	1,514,212	51.6%	456,509	15.5%	327,476	11.2%	637,696	21.7%
Other	475	100.0%	182	38.3%	136	28.6%	33	6.9%	124	26.1%
Famotidine, Injection/intravenous										
(183-day washout, 30-day gap)	687,322	100.0%	687,273	100.0%	44	0.0%	5	0.0%	0	0.0%
Female	483,157	100.0%	483,129	100.0%	24	0.0%	4	0.0%	0	0.0%
Male	204,155	100.0%	204,134	100.0%	20	0.0%	1	0.0%	0	0.0%
Other	10	100.0%	10	100.0%	0	0.0%	0	0.0%	0	0.0%
Famotidine, All										
(183-day washout, 30-day gap)	8,075,881	100.0%	4,628,519	57.3%	1,108,404	13.7%	790,562	9.8%	1,548,396	19.2%
Female	4,925,386	100.0%	2,900,778	58.9%	651,623	13.2%	462,458	9.4%	910,527	18.5%
Male	3,150,010	100.0%	1,727,549	54.8%	456,645	14.5%	328,071	10.4%	637,745	20.2%
Other	485	100.0%	192	39.6%	136	28.0%	33	6.8%	124	25.6%

Table 6c. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Age Group

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid										
(0-day washout, 0-day gap)	22,529,944	100.0%	16,598,319	73.7%	1,869,136	8.3%	3,102,369	13.8%	960,120	4.3%
<2 years	2,128,221	100.0%	1,929,729	90.7%	121,109	5.7%	43,442	2.0%	33,941	1.6%
2-11 years	812,437	100.0%	758,350	93.3%	26,833	3.3%	13,800	1.7%	13,454	1.7%
12-17 years	488,775	100.0%	448,325	91.7%	18,647	3.8%	10,310	2.1%	11,493	2.4%
18-39 years	3,015,244	100.0%	2,567,849	85.2%	200,449	6.6%	142,527	4.7%	104,419	3.5%
40-64 years	9,281,364	100.0%	6,674,826	71.9%	837,952	9.0%	1,287,165	13.9%	481,421	5.2%
65+ years	6,803,903	100.0%	4,219,240	62.0%	664,146	9.8%	1,605,125	23.6%	315,392	4.6%
Ranitidine, Injection/intravenous										
(0-day washout, 0-day gap)	887,030	100.0%	886,874	100.0%	125	0.0%	20	0.0%	11	0.0%
<2 years	5,919	100.0%	5,912	99.9%	7	0.1%	0	0.0%	0	0.0%
2-11 years	13,506	100.0%	13,497	99.9%	2	0.0%	2	0.0%	5	0.0%
12-17 years	11,704	100.0%	11,700	100.0%	4	0.0%	0	0.0%	0	0.0%
18-39 years	97,448	100.0%	97,444	100.0%	3	0.0%	1	0.0%	0	0.0%
40-64 years	488,686	100.0%	488,673	100.0%	9	0.0%	3	0.0%	1	0.0%
65+ years	269,767	100.0%	269,648	100.0%	100	0.0%	14	0.0%	5	0.0%
Ranitidine, All (0-day washout, 0-day gap)	23,416,798	100.0%	17,485,026	74.7%	1,869,260	8.0%	3,102,381	13.2%	960,131	4.1%
<2 years	2,134,839	100.0%	1,936,330	90.7%	121,123	5.7%	43,443	2.0%	33,943	1.6%
2-11 years	825,887	100.0%	771,795	93.5%	26,828	3.2%	13,805	1.7%	13,459	1.6%
12-17 years	500,840	100.0%	460,376	91.9%	18,658	3.7%	10,314	2.1%	11,492	2.3%
18-39 years	3,114,743	100.0%	2,667,237	85.6%	200,475	6.4%	142,612	4.6%	104,419	3.4%
40-64 years	9,770,264	100.0%	7,163,296	73.3%	838,018	8.6%	1,287,528	13.2%	481,422	4.9%
65+ years	7,070,225	100.0%	4,485,992	63.4%	664,158	9.4%	1,604,679	22.7%	315,396	4.5%
Famotidine, Oral solid/liquid										
(0-day washout, 0-day gap)	10,045,808	100.0%	5,734,750	57.1%	1,325,618	13.2%	1,232,005	12.3%	1,753,435	17.5%
<2 years	103,231	100.0%	98,611	95.5%	3,508	3.4%	1,012	1.0%	100	0.1%
2-11 years	105,550	100.0%	99,038	93.8%	4,095	3.9%	1,604	1.5%	813	0.8%
12-17 years	129,876	100.0%	111,526	85.9%	11,260	8.7%	3,194	2.5%	3,896	3.0%
18-39 years	1,405,854	100.0%	900,609	64.1%	210,676	15.0%	57,380	4.1%	237,189	16.9%
40-64 years	4,448,592	100.0%	2,418,801	54.4%	660,999	14.9%	481,581	10.8%	887,211	19.9%
65+ years	3,852,705	100.0%	2,106,165	54.7%	435,080	11.3%	687,234	17.8%	624,226	16.2%

Table 6c. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Age Group

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	901,750	100.0%	901,667	100.0%	61	0.0%	21	0.0%	1	0.0%
<2 years	4,007	100.0%	4,007	100.0%	0	0.0%	0	0.0%	0	0.0%
2-11 years	13,596	100.0%	13,595	100.0%	1	0.0%	0	0.0%	0	0.0%
12-17 years	16,181	100.0%	16,181	100.0%	0	0.0%	0	0.0%	0	0.0%
18-39 years	186,603	100.0%	186,599	100.0%	4	0.0%	0	0.0%	0	0.0%
40-64 years	556,009	100.0%	555,982	100.0%	23	0.0%	3	0.0%	1	0.0%
65+ years	125,354	100.0%	125,303	100.0%	33	0.0%	18	0.0%	0	0.0%
Famotidine, All (0-day washout, 0-day gap)	10,947,309	100.0%	6,636,170	60.6%	1,325,682	12.1%	1,232,021	11.3%	1,753,436	16.0%
<2 years	107,458	100.0%	102,837	95.7%	3,509	3.3%	1,012	0.9%	100	0.1%
2-11 years	119,024	100.0%	112,508	94.5%	4,095	3.4%	1,605	1.3%	816	0.7%
12-17 years	146,359	100.0%	127,972	87.4%	11,275	7.7%	3,215	2.2%	3,897	2.7%
18-39 years	1,593,222	100.0%	1,087,922	68.3%	210,675	13.2%	57,410	3.6%	237,215	14.9%
40-64 years	5,005,265	100.0%	2,975,254	59.4%	661,035	13.2%	481,755	9.6%	887,221	17.7%
65+ years	3,975,981	100.0%	2,229,677	56.1%	435,093	10.9%	687,024	17.3%	624,187	15.7%
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	12,495,048	100.0%	9,144,791	73.2%	1,028,830	8.2%	1,687,280	13.5%	634,147	5.1%
<2 years	225,474	100.0%	207,697	92.1%	10,260	4.6%	3,887	1.7%	3,630	1.6%
2-11 years	678,745	100.0%	633,085	93.3%	22,712	3.3%	10,025	1.5%	12,923	1.9%
12-17 years	399,525	100.0%	366,495	91.7%	15,193	3.8%	7,695	1.9%	10,142	2.5%
18-39 years	2,049,463	100.0%	1,750,638	85.4%	134,164	6.5%	87,626	4.3%	77,035	3.8%
40-64 years	5,409,498	100.0%	3,929,687	72.6%	481,929	8.9%	674,975	12.5%	322,907	6.0%
65+ years	3,732,343	100.0%	2,257,189	60.5%	364,572	9.8%	903,072	24.2%	207,510	5.6%
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	654,950	100.0%	654,834	100.0%	89	0.0%	16	0.0%	11	0.0%
<2 years	1,645	100.0%	1,639	99.6%	6	0.4%	0	0.0%	0	0.0%
2-11 years	8,419	100.0%	8,412	99.9%	1	0.0%	1	0.0%	5	0.1%
12-17 years	8,378	100.0%	8,378	100.0%	0	0.0%	0	0.0%	0	0.0%
18-39 years	69,287	100.0%	69,287	100.0%	0	0.0%	0	0.0%	0	0.0%
40-64 years	356,283	100.0%	356,273	100.0%	7	0.0%	2	0.0%	1	0.0%
65+ years	210,938	100.0%	210,845	100.0%	75	0.0%	13	0.0%	5	0.0%

Table 6c. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, by Length Categories, in Days, by Age Group

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, All (183-day washout, 30-day gap)	13,184,623	100.0%	9,832,222	74.6%	1,029,331	7.8%	1,688,895	12.8%	634,175	4.8%
<2 years	227,814	100.0%	210,024	92.2%	10,270	4.5%	3,889	1.7%	3,631	1.6%
2-11 years	689,301	100.0%	643,608	93.4%	22,728	3.3%	10,037	1.5%	12,928	1.9%
12-17 years	409,032	100.0%	375,970	91.9%	15,216	3.7%	7,704	1.9%	10,142	2.5%
18-39 years	2,124,986	100.0%	1,825,936	85.9%	134,220	6.3%	87,790	4.1%	77,040	3.6%
40-64 years	5,781,220	100.0%	4,300,101	74.4%	482,195	8.3%	676,004	11.7%	322,920	5.6%
65+ years	3,952,270	100.0%	2,476,583	62.7%	364,702	9.2%	903,471	22.9%	207,514	5.3%
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	7,359,176	100.0%	3,913,666	53.2%	1,108,049	15.1%	789,207	10.7%	1,548,254	21.0%
<2 years	13,610	100.0%	13,045	95.8%	481	3.5%	74	0.5%	10	0.1%
2-11 years	78,078	100.0%	73,258	93.8%	3,154	4.0%	1,036	1.3%	630	0.8%
12-17 years	104,519	100.0%	88,700	84.9%	9,841	9.4%	2,562	2.5%	3,416	3.3%
18-39 years	1,078,013	100.0%	659,475	61.2%	173,887	16.1%	41,889	3.9%	202,762	18.8%
40-64 years	3,304,339	100.0%	1,655,213	50.1%	561,506	17.0%	307,662	9.3%	779,958	23.6%
65+ years	2,780,617	100.0%	1,423,975	51.2%	359,180	12.9%	435,984	15.7%	561,478	20.2%
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	687,322	100.0%	687,273	100.0%	44	0.0%	5	0.0%	0	0.0%
<2 years	1,025	100.0%	1,025	100.0%	0	0.0%	0	0.0%	0	0.0%
2-11 years	7,139	100.0%	7,138	100.0%	1	0.0%	0	0.0%	0	0.0%
12-17 years	11,702	100.0%	11,702	100.0%	0	0.0%	0	0.0%	0	0.0%
18-39 years	138,174	100.0%	138,170	100.0%	4	0.0%	0	0.0%	0	0.0%
40-64 years	429,590	100.0%	429,569	100.0%	19	0.0%	2	0.0%	0	0.0%
65+ years	99,692	100.0%	99,669	100.0%	20	0.0%	3	0.0%	0	0.0%
Famotidine, All (183-day washout, 30-day gap)	8,075,881	100.0%	4,628,519	57.3%	1,108,404	13.7%	790,562	9.8%	1,548,396	19.2%
<2 years	14,903	100.0%	14,338	96.2%	481	3.2%	74	0.5%	10	0.1%
2-11 years	85,507	100.0%	80,680	94.4%	3,158	3.7%	1,036	1.2%	633	0.7%
12-17 years	117,103	100.0%	101,222	86.4%	9,871	8.4%	2,591	2.2%	3,419	2.9%
18-39 years	1,222,478	100.0%	803,674	65.7%	173,917	14.2%	42,082	3.4%	202,805	16.6%
40-64 years	3,749,790	100.0%	2,099,698	56.0%	561,650	15.0%	308,369	8.2%	780,073	20.8%
65+ years	2,886,100	100.0%	1,528,907	53.0%	359,327	12.5%	436,410	15.1%	561,456	19.5%

Table 7a. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, Overall

Exposure	Form	Design	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine	Oral	0-day washout, 0-day gap	22,529,944	41.73	25.02	1	30	30	41	999
Ranitidine	Inj/IV[1]	0-day washout, 0-day gap	887,030	1.15	1.87	1	1	1	1	188
Ranitidine	Any	0-day washout, 0-day gap	23,416,798	40.19	25.74	1	30	30	31	999
Famotidine	Oral	0-day washout, 0-day gap	10,045,808	50.43	31.00	1	30	30	90	999
Famotidine	Inj/IV	0-day washout, 0-day gap	901,750	1.17	1.74	1	1	1	1	100
Famotidine	Any	0-day washout, 0-day gap	10,947,309	46.38	32.64	1	30	30	90	999
Ranitidine	Oral	183-day washout, 30-day gap	12,495,048	42.02	25.56	1	30	30	50	999
Ranitidine	Inj/IV	183-day washout, 30-day gap	654,950	1.14	1.88	1	1	1	1	188
Ranitidine	Any	183-day washout, 30-day gap	13,184,623	39.92	26.47	1	30	30	31	999
Famotidine	Oral	183-day washout, 30-day gap	7,359,176	52.38	31.74	1	30	30	90	999
Famotidine	Inj/IV	183-day washout, 30-day gap	687,322	1.15	1.63	1	1	1	1	90
Famotidine	Any	183-day washout, 30-day gap	8,075,881	47.89	33.58	1	30	30	90	999

[1]Injection/Intravenous

Table 7b. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Sex

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	22,529,944	41.73	25.02	1	30	30	41	999
Female	13,366,299	41.43	24.86	1	30	30	31	999
Male	9,163,113	42.15	25.26	1	30	30	50	900
Other	532	44.05	28.19	2	30	30	50	100
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	887,030	1.15	1.87	1	1	1	1	188
Female	599,411	1.14	1.81	1	1	1	1	188
Male	287,480	1.17	1.99	1	1	1	1	180
Other	139	1	0	1	1	1	1	1
Ranitidine, Oral solid/liquid or Injection/intravenous (0-day washout, 0-day gap)	23,416,798	40.19	25.74	1	30	30	31	999
Female	13,965,611	39.71	25.65	1	30	30	30	999
Male	9,450,516	40.91	25.85	1	30	30	44	900
Other	671	35.13	30.57	1	14	30	33	100
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	10,045,808	50.43	31	1	30	30	90	999
Female	6,002,633	49.83	30.87	1	30	30	90	786
Male	4,042,628	51.32	31.16	1	30	30	90	999
Other	547	56.69	30.72	1	30	50	100	100
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	901,750	1.17	1.74	1	1	1	1	100
Female	631,968	1.17	1.71	1	1	1	1	100
Male	269,770	1.19	1.81	1	1	1	1	90
Other	12	1	0	1	1	1	1	1
Famotidine, Oral solid/liquid or Injection/intravenous (0-day washout, 0-day gap)	10,947,309	46.38	32.64	1	30	30	90	999
Female	6,634,432	45.2	32.66	1	30	30	90	786
Male	4,312,318	48.18	32.52	1	30	30	90	999
Other	559	55.49	31.44	1	30	50	100	100
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	12,495,048	42.02	25.56	1	30	30	50	999
Female	7,683,131	41.6	25.29	1	30	30	39	999
Male	4,811,584	42.7	25.97	1	30	30	50	579
Other	333	48.08	30.12	5	30	30	90	100
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	654,950	1.14	1.88	1	1	1	1	188
Female	445,204	1.13	1.83	1	1	1	1	188
Male	209,623	1.16	1.99	1	1	1	1	180
Other	123	1	0	1	1	1	1	1

Table 7b. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Sex

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid or Injection/intravenous (183-day washout, 30-day gap)	13,184,623	39.92	26.47	1	30	30	31	999
Female	8,151,137	39.32	26.27	1	30	30	30	999
Male	5,033,030	40.9	26.77	1	30	30	50	579
Other	456	35.38	33.16	1	1	30	50	100
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	7,359,176	52.38	31.74	1	30	30	90	999
Female	4,422,808	51.76	31.65	1	30	30	90	786
Male	2,935,893	53.3	31.85	1	30	30	90	999
Other	475	56.86	30.83	1	30	50	100	100
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	687,322	1.15	1.63	1	1	1	1	90
Female	483,157	1.15	1.59	1	1	1	1	84
Male	204,155	1.17	1.74	1	1	1	1	90
Other	10	1	0	1	1	1	1	1
Famotidine, Oral solid/liquid or Injection/intravenous (183-day washout, 30-day gap)	8,075,881	47.89	33.58	1	30	30	90	999
Female	4,925,386	46.66	33.64	1	30	30	90	786
Male	3,150,010	49.82	33.39	1	30	30	90	999
Other	485	55.71	31.53	1	30	50	100	100

Table 7c. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	22,529,944	41.73	25.02	1	30	30	41	999
<2 years	2,128,221	31.24	13.58	1	30	30	30	591
2-11 years	812,437	29.25	14.48	1	30	30	30	480
12-17 years	488,775	31.29	15.82	1	30	30	30	300
18-39 years	3,015,244	35.01	19.4	1	30	30	30	365
40-64 years	9,281,364	43.04	25.4	1	30	30	50	999
65+ years	6,803,903	48.43	28.24	1	30	30	90	900
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	887,030	1.15	1.87	1	1	1	1	188
<2 years	5,919	1.7	3.31	1	1	1	1	40
2-11 years	13,506	1.26	3.76	1	1	1	1	188
12-17 years	11,704	1.2	1.35	1	1	1	1	42
18-39 years	97,448	1.03	0.77	1	1	1	1	90
40-64 years	488,686	1.04	0.89	1	1	1	1	120
65+ years	269,767	1.35	2.95	1	1	1	1	180
Ranitidine, All (0-day washout, 0-day gap)	23,416,798	40.19	25.74	1	30	30	31	999
<2 years	2,134,839	31.15	13.65	1	30	30	30	591
2-11 years	825,887	28.8	14.8	1	30	30	30	480
12-17 years	500,840	30.57	16.28	1	30	30	30	300
18-39 years	3,114,743	33.94	20	1	30	30	30	365
40-64 years	9,770,264	40.95	26.4	1	30	30	50	999
65+ years	7,070,225	46.64	29.13	1	30	30	90	900
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	10,045,808	50.43	31	1	30	30	90	999
<2 years	103,231	28.44	8.71	1	28	30	30	300
2-11 years	105,550	27.32	13.46	1	24	30	30	461
12-17 years	129,876	30.65	19.08	1	28	30	30	365
18-39 years	1,405,854	44.38	29.7	1	30	30	50	900
40-64 years	4,448,592	52.06	31.05	1	30	30	90	999
65+ years	3,852,705	52.65	31.44	1	30	30	90	828
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	901,750	1.17	1.74	1	1	1	1	100
<2 years	4,007	1.14	1.59	1	1	1	1	30
2-11 years	13,596	1.12	1.61	1	1	1	1	31
12-17 years	16,181	1.04	0.57	1	1	1	1	30
18-39 years	186,603	1.07	0.87	1	1	1	1	50
40-64 years	556,009	1.08	1.06	1	1	1	1	100
65+ years	125,354	1.75	3.87	1	1	1	1	90

Table 7c. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, All (0-day washout, 0-day gap)	10,947,309	46.38	32.64	1	30	30	90	999
<2 years	107,458	27.41	10.01	1	25	30	30	300
2-11 years	119,024	24.33	15.19	1	15	30	30	461
12-17 years	146,359	27.35	20.27	1	14	30	30	365
18-39 years	1,593,222	39.29	31.19	1	25	30	50	900
40-64 years	5,005,265	46.39	33.37	1	30	30	90	999
65+ years	3,975,981	51.06	32.2	1	30	30	90	828
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	12,495,048	42.02	25.56	1	30	30	50	999
<2 years	225,474	30.22	13.71	1	30	30	30	380
2-11 years	678,745	29.23	14.61	1	30	30	30	407
12-17 years	399,525	31.26	15.93	1	30	30	30	300
18-39 years	2,049,463	34.8	19.44	1	30	30	30	365
40-64 years	5,409,498	42.6	25.42	1	30	30	50	999
65+ years	3,732,343	49.35	28.85	1	30	30	90	687
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	654,950	1.14	1.88	1	1	1	1	188
<2 years	1,645	1.48	3.19	1	1	1	1	31
2-11 years	8,419	1.19	4.27	1	1	1	1	188
12-17 years	8,378	1.13	1	1	1	1	1	30
18-39 years	69,287	1.03	0.6	1	1	1	1	30
40-64 years	356,283	1.04	0.87	1	1	1	1	120
65+ years	210,938	1.34	2.95	1	1	1	1	180
Ranitidine, All (183-day washout, 30-day gap)	13,184,623	39.92	26.47	1	30	30	31	999
<2 years	227,814	29.96	13.92	1	30	30	30	380
2-11 years	689,301	28.83	14.89	1	30	30	30	407
12-17 years	409,032	30.6	16.35	1	30	30	30	300
18-39 years	2,124,986	33.64	20.06	1	30	30	30	365
40-64 years	5,781,220	39.97	26.59	1	30	30	37	999
65+ years	3,952,270	46.7	30.1	1	30	30	90	687
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	7,359,176	52.38	31.74	1	30	30	90	999
<2 years	13,610	26.77	8.72	1	25	30	30	120
2-11 years	78,078	27.05	13.48	1	20	30	30	461
12-17 years	104,519	30.83	19.62	1	25	30	30	365
18-39 years	1,078,013	45.85	30.52	1	30	30	50	900
40-64 years	3,304,339	54.13	31.67	1	30	30	90	999
65+ years	2,780,617	54.48	32.08	1	30	30	90	400

Table 7c. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	687,322	1.15	1.63	1	1	1	1	90
<2 years	1,025	1.23	1.43	1	1	1	1	30
2-11 years	7,139	1.09	1.33	1	1	1	1	31
12-17 years	11,702	1.03	0.47	1	1	1	1	30
18-39 years	138,174	1.05	0.74	1	1	1	1	50
40-64 years	429,590	1.07	1	1	1	1	1	90
65+ years	99,692	1.67	3.58	1	1	1	1	84
Famotidine, All (183-day washout, 30-day gap)	8,075,881	47.89	33.58	1	30	30	90	999
<2 years	14,903	24.79	10.81	1	25	30	30	120
2-11 years	85,507	24.82	14.8	1	16	30	30	461
12-17 years	117,103	27.76	20.65	1	14	30	30	365
18-39 years	1,222,478	40.63	32.05	1	25	30	50	900
40-64 years	3,749,790	47.89	34.29	1	30	30	90	999
65+ years	2,886,100	52.59	32.99	1	30	30	90	400

Table 8a. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, Overall

Exposure	Form	Design	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine	Oral	0-day washout, 0-day gap	9,102,105	103.74	358.64	1	5	18	55	6,866
Ranitidine	Inj/IV[1]	0-day washout, 0-day gap	545,316	30.10	126.68	1	6	13	20	5,878
Ranitidine	Any	0-day washout, 0-day gap	9,661,387	101.12	353.93	1	5	17	52	6,866
Famotidine	Oral	0-day washout, 0-day gap	4,065,126	150.37	456.68	1	6	24	81	6,544
Famotidine	Inj/IV	0-day washout, 0-day gap	406,899	38.91	151.09	1	6	12	20	5,503
Famotidine	Any	0-day washout, 0-day gap	4,484,526	142.18	442.44	1	6	21	74	6,544
Ranitidine	Oral	183-day washout, 30-day gap	2,244,729	278.18	560.96	31	49	91	228	6,704
Ranitidine	Inj/IV	183-day washout, 30-day gap	36,835	212.91	375.59	31	41	67	195	5,878
Ranitidine	Any	183-day washout, 30-day gap	2,298,625	281.02	563.43	31	49	91	231	6,704
Famotidine	Oral	183-day washout, 30-day gap	1,493,396	336.79	651.88	31	53	99	268	6,338
Famotidine	Inj/IV	183-day washout, 30-day gap	37,086	248.97	385.33	31	48	94	277	5,503
Famotidine	Any	183-day washout, 30-day gap	1,542,929	337.78	649.61	31	53	100	272	6,338

[1]Injection/Intravenous

Table 8b. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Sex

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	9,102,105	103.74	358.64	1	5	18	55	6,866
Female	5,512,471	113.57	382.61	1	5	19	59	6,814
Male	3,589,444	88.65	317.76	1	5	16	50	6,866
Other	190	118.19	304.42	1	6	22	79	2,747
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	545,316	30.1	126.68	1	6	13	20	5,878
Female	379,674	30.12	126.95	1	6	13	20	4,903
Male	165,526	30.06	126.06	1	6	13	20	5,878
Other	116	19.04	73.22	5	6	6	20	793
Ranitidine, All (0-day washout, 0-day gap)	9,661,387	101.12	353.93	1	5	17	52	6,866
Female	5,902,478	110.01	376.23	1	5	18	55	6,814
Male	3,758,601	87.18	315.23	1	5	16	48	6,866
Other	308	85.62	262.91	1	6	13	31	2,747
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	4,065,126	150.37	456.68	1	6	24	81	6,544
Female	2,455,741	164.39	481.69	1	7	26	88	6,524
Male	1,609,146	128.97	414.72	1	6	21	71	6,544
Other	239	131.73	329.7	1	8	24	100	2,355
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	406,899	38.91	151.09	1	6	12	20	5,503
Female	303,397	37.92	150.89	1	6	9	20	5,503
Male	103,495	41.82	151.62	1	6	13	20	4,321
Other	7	13.29	6.05	5	6	13	20	20
Famotidine, All (0-day washout, 0-day gap)	4,484,526	142.18	442.44	1	6	21	74	6,544
Female	2,767,815	152.71	462.65	1	6	21	78	6,524
Male	1,716,465	125.22	407.19	1	6	20	67	6,544
Other	246	128.36	325.56	1	8	22	97	2,355
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,244,729	278.18	560.96	31	49	91	228	6,704
Female	1,438,692	296.2	587.98	31	50	94	245	6,704
Male	805,991	245.99	507.61	31	48	86	200	6,670
Other	46	352.67	519.58	31	57	139	369	2,747
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	36,835	212.91	375.59	31	41	67	195	5,878
Female	24,234	223.72	384.37	31	41	69	215	4,903
Male	12,597	192.09	357.2	31	41	62	167	5,878
Other	4	239.75	369.49	32	41	67	439	793

Table 8b. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Sex

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, All (183-day washout, 30-day gap)	2,298,625	281.02	563.43	31	49	91	231	6,704
Female	1,475,174	299.32	590.22	31	50	94	249	6,704
Male	823,400	248.22	510.29	31	48	86	202	6,670
Other	51	368.78	533.24	31	57	136	375	2,747
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,493,396	336.79	651.88	31	53	99	268	6,338
Female	936,427	357.21	674.87	31	54	103	293	6,338
Male	556,866	302.46	609.77	31	52	93	230	6,073
Other	103	284.91	459.37	32	49	103	270	2,355
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	37,086	248.97	385.33	31	48	94	277	5,503
Female	25,836	256.56	394.96	31	48	97	288	5,503
Male	11,250	231.54	361.65	31	48	89	249	4,321
Other	0	-	-	-	-	-	-	-
Famotidine, All (183-day washout, 30-day gap)	1,542,929	337.78	649.61	31	53	100	272	6,338
Female	970,938	357.91	671.87	31	54	104	298	6,338
Male	571,888	303.59	608.46	31	52	93	233	6,093
Other	103	284.91	459.37	32	49	103	270	2,355

Table 8c. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	9,102,105	103.74	358.64	1	5	18	55	6,866
<2 years	524,886	105.38	380.27	1	5	14	39	6,442
2-11 years	300,222	195.05	490.86	1	8	28	119	6,620
12-17 years	201,567	204.02	518.29	1	8	29	122	6,601
18-39 years	1,296,648	164.92	498.82	1	6	24	80	6,800
40-64 years	4,078,642	94.11	339.08	1	5	18	54	6,855
65+ years	2,700,140	70.96	246.56	1	4	15	46	6,866
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	545,316	30.1	126.68	1	6	13	20	5,878
<2 years	2,984	16.45	74.1	1	6	6	7	1,784
2-11 years	5,243	30.49	135.32	1	6	6	13	2,697
12-17 years	2,964	62.39	244.44	1	6	6	20	3,791
18-39 years	37,819	53.14	204.98	1	6	13	20	4,455
40-64 years	311,779	29.38	126.84	1	6	13	20	5,878
65+ years	184,527	26.28	99.56	1	6	13	20	3,777
Ranitidine, All (0-day washout, 0-day gap)	9,661,387	101.12	353.93	1	5	17	52	6,866
<2 years	528,481	105.31	380.3	1	5	14	38	6,442
2-11 years	306,085	193.57	490.02	1	8	27	117	6,620
12-17 years	205,499	204.58	519.56	1	8	29	121	6,601
18-39 years	1,340,949	164.59	498.24	1	6	23	79	6,800
40-64 years	4,396,209	91.01	333.13	1	5	17	50	6,855
65+ years	2,884,164	69.08	243.09	1	4	14	43	6,866
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	4,065,126	150.37	456.68	1	6	24	81	6,544
<2 years	31,079	48.09	221.61	1	4	10	25	5,677
2-11 years	36,719	123.83	411.56	1	6	18	59	6,068
12-17 years	42,322	223.42	561.59	1	8	29	125	5,836
18-39 years	526,382	273.71	646.21	1	11	41	176	6,487
40-64 years	1,966,433	154.79	465.43	1	7	27	86	6,544
65+ years	1,462,191	100.74	339.67	1	5	17	57	5,971
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	406,899	38.91	151.09	1	6	12	20	5,503
<2 years	2,039	19.2	118.32	1	6	6	6	2,861
2-11 years	5,031	25.86	129.8	1	6	6	7	3,247
12-17 years	2,657	111.38	320.15	1	6	6	40	4,321
18-39 years	45,619	74.41	235.32	1	6	12	26	4,035
40-64 years	280,223	34.67	138.07	1	6	12	20	5,503
65+ years	71,330	31.66	115.55	1	6	13	20	3,599

Table 8c. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, All (0-day washout, 0-day gap)	4,484,526	142.18	442.44	1	6	21	74	6,544
<2 years	33,222	47.23	220.8	1	4	10	24	5,677
2-11 years	41,784	114.9	397.7	1	6	14	51	6,068
12-17 years	45,489	221.85	558.04	1	7	27	124	5,862
18-39 years	576,673	261.18	629.81	1	10	37	163	6,487
40-64 years	2,252,823	141.7	443.16	1	6	22	75	6,544
65+ years	1,534,535	98.62	335.36	1	5	17	55	5,971
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,244,729	278.18	560.96	31	49	91	228	6,704
<2 years	28,839	391.78	675.21	31	51	110	362	6,036
2-11 years	128,498	406.1	653.42	31	59	139	425	6,620
12-17 years	83,735	411.04	679.85	31	58	133	423	6,389
18-39 years	407,786	374.47	703.85	31	53	107	327	6,670
40-64 years	1,014,869	249.21	532.17	31	48	86	199	6,704
65+ years	581,002	208.11	412.34	31	48	83	179	6,547
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	36,835	212.91	375.59	31	41	67	195	5,878
<2 years	49	211.53	308.08	33	48	75	203	1,347
2-11 years	316	265.76	417.57	31	43	82	283	2,697
12-17 years	378	351.03	528.33	31	50	124	390	3,791
18-39 years	3,834	311.22	469.34	31	52	114	363	3,697
40-64 years	18,868	224.2	398.48	31	41	69	202	5,878
65+ years	13,390	163.71	288.08	31	40	58	147	3,777
Ranitidine, All (183-day washout, 30-day gap)	2,298,625	281.02	563.43	31	49	91	231	6,704
<2 years	29,016	393.19	676.97	31	51	111	364	6,036
2-11 years	129,469	407.67	655.5	31	59	139	427	6,620
12-17 years	84,941	414.75	682.73	31	58	134	428	6,389
18-39 years	416,303	379.41	706.87	31	53	109	334	6,670
40-64 years	1,041,050	252.64	535.47	31	48	86	202	6,704
65+ years	597,846	210.05	414.73	31	48	83	180	6,547
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,493,396	336.79	651.88	31	53	99	268	6,338
<2 years	1,066	249.72	508.77	31	46	79	200	4,980
2-11 years	10,566	335.05	654.81	31	50	99	270	6,068
12-17 years	17,007	460.86	747.16	31	58	138	480	5,836
18-39 years	243,264	484.52	804.43	31	62	146	483	6,129
40-64 years	772,520	328.86	649.67	31	53	97	255	6,338
65+ years	448,973	265.93	535.94	31	50	89	203	5,971

Table 8c. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2000 through April 30, 2019, in Days, by Age Group

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	37,086	248.97	385.33	31	48	94	277	5,503
<2 years	26	476.81	715.72	33	84	159	619	2,861
2-11 years	229	300.13	452.24	31	55	118	338	3,247
12-17 years	558	423.57	556.92	31	69	197	515	4,321
18-39 years	7,060	322.47	437.13	31	62	158	391	4,035
40-64 years	22,952	236.81	376.19	31	47	89	253	5,503
65+ years	6,261	192.31	308.75	31	41	69	192	3,599
Famotidine, All (183-day washout, 30-day gap)	1,542,929	337.78	649.61	31	53	100	272	6,338
<2 years	1,116	260	520.38	31	46	81	209	4,980
2-11 years	10,926	339.65	658.92	31	50	101	276	6,068
12-17 years	17,946	466.71	747.03	31	59	143	499	5,862
18-39 years	253,714	483.73	798.99	31	63	148	487	6,129
40-64 years	801,782	329.12	646.02	31	53	98	259	6,338
65+ years	457,445	267.08	535.96	31	50	89	205	5,971

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (October 28, 2019)

DP ID	DP Start Date[1]	DP End Date[1]
DP02	1/1/2000	1/31/2019
DP03	1/1/2005	7/31/2018
DP04	1/1/2008	12/31/2018
DP05	1/1/2008	11/30/2018
DP06	1/1/2000	6/30/2018
DP07	1/1/2006	12/31/2018
DP08	1/1/2000	4/30/2019
DP09	1/1/2000	2/28/2019
DP10	6/1/2007	1/31/2019
DP11	1/1/2000	12/31/2018
DP12	1/1/2004	3/31/2019
DP13	1/1/2000	3/31/2018
DP14	1/1/2000	12/31/2017
DP15	1/1/2000	4/30/2018
DP16	1/1/2012	6/30/2017

[1]The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of Generic and Brand Drug Names Used to Define Exposures and Incidence Criteria in this Request

Generic Name	Brand Name
Oral Ranitidine	
Ranitidine Hcl/Dietary Supplement No.17	Gabitidine
Ranitidine Hcl/Dietary Supplement No.8	Sentradine
Ranitidine Bismuth Citrate	Tritec
Ranitidine Hcl	ranitidine HCl
Ranitidine Hcl	Acid Reducer (ranitidine)
Ranitidine Hcl	Zantac
Ranitidine Hcl	Zantac 150 EFFERdose
Ranitidine Hcl	Zantac GELdose
Ranitidine Hcl	Zantac 25 EFFERdose
Ranitidine Hcl	Wal-Zan 150
Ranitidine Hcl	Wal-Zan 75
Ranitidine Hcl	Zantac 75
Ranitidine Hcl	Zantac Maximum Strength
Ranitidine Hcl	Taladine
Ranitidine Hcl	Acid Control (ranitidine)
Ranitidine Hcl	Heartburn Relief (ranitidine)
Ranitidine Hcl	Deprizine
Injection/Intravenous Ranitidine	
Ranitidine Hcl	Zantac
Ranitidine Hcl	Ranitidine HCl
Ranitidine Hcl In 0.45 % Sodium Chloride	Zantac in 0.45 % sod. chloride
Oral Famotidine	
Famotidine/Calcium Carbonate/Magnesium Hydroxide	Pepcid Complete
Famotidine/Calcium Carbonate/Magnesium Hydroxide	Dual Action Complete
Famotidine/Calcium Carbonate/Magnesium Hydroxide	Complete
Famotidine/Calcium Carbonate/Magnesium Hydroxide	Acid Reducer Complete (famot)
Famotidine/Calcium Carbonate/Magnesium Hydroxide	Duo Fusion
Famotidine/Calcium Carbonate/Magnesium Hydroxide	Tums Dual Action (famotidine)
Famotidine/Calcium Carbonate/Magnesium Hydroxide	Acid Controller Complete
Ibuprofen/Famotidine	Duexis
Famotidine	Pepcid
Famotidine	Pepcid RPD
Famotidine	famotidine
Famotidine	Acid Reducer (famotidine)
Famotidine	Acid Controller
Famotidine	Heartburn Relief (famotidine)
Famotidine	Pepcid AC
Famotidine	Mylanta AR
Famotidine	Heartburn Prevention
Injection/Intravenous Famotidine	
Famotidine	Famotidine
Famotidine	Pepcid
Famotidine In 0.9 % Sodium Chloride	Famotidine in 0.9 % NaCl
Famotidine In Sodium Chloride, Iso-Osmotic/Pf	Pepcid in NaCl (iso-osm) (PF)
Famotidine In Sodium Chloride, Iso-Osmotic/Pf	Famotidine (PF)-NaCl (iso-os)
Famotidine/Pf	Famotidine (PF)
Famotidine/Pf	Pepcid (PF)

Appendix B. List of Generic and Brand Drug Names Used to Define Exposures and Incidence Criteria in this Request

Generic Name	Brand Name
Cimetidine (All Forms)	
Cimetidine	Cimetidine
Cimetidine	Tagamet
Cimetidine	Heartburn Relief (cimetidine)
Cimetidine	Tagamet HB
Cimetidine	Acid Reducer (cimetidine)
Cimetidine	Heartburn 200
Cimetidine	Acid Relief (cimetidine)
Cimetidine	Heartburn
Cimetidine Hcl	Cimetidine HCl
Cimetidine Hcl	Tagamet
Cimetidine Hcl In 0.9 % Sodium Chloride	Cimetidine in 0.9 % NaCl
Nizatidine (All Forms)	
Nizatidine	Axid
Nizatidine	Nizatidine
Nizatidine	Tagamet
Nizatidine	Axid AR

Appendix C. List of Healthcare Common Procedure Coding System (HCPCS) codes to Define Exposures and Incidence Criteria in this Request

Code	Description	Code Type	Code Category
	Ranitidine Injection		
J2780	Injection, ranitidine hydrochloride, 25 mg	HC	Procedure
	Famotidine Injection		
S0028	Injection, famotidine, 20 mg	HC	Procedure
	Cimetidine Injection		
S0023	Injection, cimetidine hydrochloride, 300 mg	HC	Procedure

Appendix D. List of Generic and Brand Drug Names Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Proton-Pump Inhibitor (All Forms)	
Omeprazole Magnesium	Acid Reducer (omeprazole)
Rabeprazole Sodium	AcipHex
Rabeprazole Sodium	AcipHex Sprinkle
Dexlansoprazole	Dexilant
Esomeprazole Magnesium/Glycerin	Esomep-EZS
Esomeprazole Magnesium	Esomeprazole magnesium
Esomeprazole Sodium	Esomeprazole sodium
Esomeprazole Strontium	Esomeprazole strontium
Lansoprazole	FIRST-Lansoprazole
Omeprazole	FIRST-Omeprazole
Lansoprazole	Heartburn Relief 24 Hour
Esomeprazole Magnesium	Heartburn Treatment
Lansoprazole	Heartburn Treatment 24 Hour
Dexlansoprazole	Kapidex
Lansoprazole	lansoprazole
Esomeprazole Magnesium	Nexium
Esomeprazole Magnesium	Nexium 24HR
Esomeprazole Sodium	Nexium IV
Esomeprazole Magnesium	Nexium Packet
Omeprazole/Sodium Bicarbonate	OmePPi
Omeprazole	Omeprazole
Omeprazole Magnesium	Omeprazole magnesium
Omeprazole	Omeprazole+SyrSpend SF Alka
Omeprazole/Sodium Bicarbonate	Omeprazole-sodium bicarbonate
Pantoprazole Sodium	Pantoprazole
Lansoprazole	Prevacid
Lansoprazole	Prevacid 24Hr
Lansoprazole	Prevacid IV
Lansoprazole/Naproxen	PREVACID NapraPAC
Lansoprazole	Prevacid SoluTab
Omeprazole	Prilosec
Omeprazole Magnesium	Prilosec
Omeprazole Magnesium	Prilosec OTC
Pantoprazole Sodium	Protonix
Rabeprazole Sodium	Rabeprazole
Omeprazole/Sodium Bicarbonate	Zegerid
Omeprazole/Sodium Bicarbonate	Zegerid OTC

Appendix E. List of Healthcare Common Procedure Coding System (HCPCS) codes to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
	Proton Pump Inhibitor Injection		
S0164	Injection, pantoprazole sodium, 40 mg	HC	Procedure
C9113	Injection, pantoprazole sodium, per vial	HC	Procedure

Appendix F. Specifications Defining Parameters for this Request

The Center for Drug Evaluation and Research (CDER) has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1, to assess the use patterns of ranitidine and a comparator agent, famotidine, within the Sentinel Distributed Database (SDD).

Query period: January 1, 2000 - April 30, 2019
Coverage requirement: Medical and Drug
Pre-index enrollment requirement: Minimum required; currently equals the number of washout days (see scenarios below)
Post-index enrollment requirement: 0 days
Enrollment gap: 45 days
Age groups: 0-1, 2-11, 12-17, 18-39, 40-64, 65+ years
Stratifications: Overall, sex, and age group
Censor output categorization: N/A
Restrictions: N/A
Distribution of index-defining codes: Not requested
Envelope macro: Default (Reclassify encounters during inpatient stay as inpatient)
Freeze data: Not requested
Data Source: All Sentinel Data Partners

	Exposure														Baseline Characteristics
Scenario	Index exposure	Index exposure form	Cohort definition	Pre-index enrollment requirement	Incident exposure washout period	Incident with respect to:	Incidence evaluation	Episode gap	Episode extension	Minimum episode duration	Minimum days supplied	Maximum episode duration	Forced Days Supplied	Censor episode at evidence of:	
1	Ranitidine	Oral solid/liquid	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
2	Ranitidine	Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
3	Ranitidine	Oral solid/liquid or Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
4	Famotidine	Oral solid/liquid	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G

Appendix F. Specifications Defining Parameters for this Request														
5	Famotidine	Injection/intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
6	Famotidine	Oral solid/liquid or Injection/intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
7	Ranitidine	Oral solid/liquid	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
8	Ranitidine	Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
9	Ranitidine	Oral solid/liquid or Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
10	Famotidine	Oral solid/liquid	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
11	Famotidine	Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	ho	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
12	Famotidine	Oral solid/liquid or Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360.
NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix G. Specifications Defining Baseline Characteristic Parameters in this Request

Baseline Characteristics	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply If Covariate Includes Dispensings	Number of Instances the Covariate Should Be Found in Evaluation Period
OTC products	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
PPIs	Pharmacy Dispensings	N/A	Day 1	End of patients' follow-up	Evaluation period should search for only evidence of a dispensing date	1
ALL OTHER	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
AHP	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Amneal Pharmace	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Apotex Corp	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Bedford Labs	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Boehringer Cons	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Boehringer/Chat	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Chattem Cons Pr	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Covis Pharmaceu	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Covis/Teligent	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Dr.Reddy's Lab	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Glaxo Pharm	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Glaxosmithkline	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Glenmark Pharma	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Gsms, Inc.	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1

Appendix G. Specifications Defining Baseline Characteristic Parameters in this Request

Baseline Characteristics	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply If Covariate Includes Dispensings	Number of Instances the Covariate Should Be Found in Evaluation Period
Hi-Tech/Akorn C	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Major Pharmaceu	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Mylan	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Mylan Instituti	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Par Pharm.	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Pfizer Cons.Hlt	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Pharmaceutical	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Precision Dose	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Ranbaxy Pharmac	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Sandoz	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Silarx/Lannett	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Strides Pharma	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Teligent Pharma	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Teva Usa	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Watson Labs	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Wockhardt Usa L	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Zydus Pharmaceu	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1