

“FDA Adverse Event Reporting System (FAERS) Public Dashboard”

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DISCLAIMER



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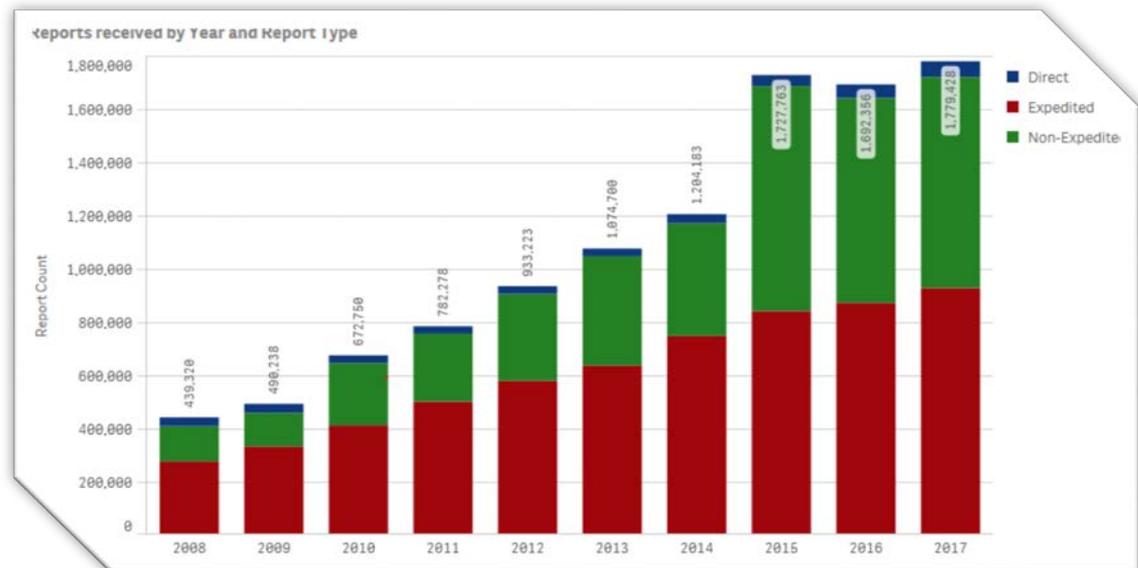
LEARNING OBJECTIVES

- Describe the FAERS public database
- Demonstrate how to use the FAERS public dashboard to view adverse event reporting metrics
- Illustrate use of FAERS public dashboard to view adverse event information on a specific product

BACKGROUND

The FDA Adverse Events Reporting System (FAERS) is a database that contains spontaneous adverse event reports that are submitted to FDA from the product manufacturer or directly from the consumer, healthcare professional, or other reporter. The database supports the FDA's post marketing safety surveillance program for drug and therapeutic biologic products.

The database consists of more than fourteen (14) million reports since 1969 to August 2017. Each year, FDA receives over one (1) million adverse events and medication error reports associated with the use of drug or biologic products. Existence of a report does not establish causation.



OBJECTIVE

FDA provides information to the public in an accessible and transparent manner. This new FAERS dashboard gives the public and industry a more user friendly platform for accessing FAERS reports and making adverse event data more accessible and transparent.

FAERS data outlets for public:

The image displays three panels representing different data outlets for FAERS. The first panel, 'Open FDA', features the 'openFDA' logo and a blue callout box labeled 'JSON File(s)'. The second panel, 'FAERS Quarterly Data Extracts (QDE)', shows a screenshot of the FDA website with a blue callout box labeled 'Text/ASCII Files and XML File(s)'. The third panel, 'FAERS Public Dashboard', shows a dashboard with a bar chart and a red star labeled 'NEW', with a blue callout box labeled 'Easy Interactive Access'. The 'Open FDA' panel also includes the text 'Open FDA' below the logo.

JSON File(s)

Text/ASCII Files and XML File(s)

NEW

Easy Interactive Access

Open FDA

FAERS Quarterly Data Extracts (QDE)

FAERS Public Dashboard

The FAERS Public Dashboard is an interactive application, which enables the user to search for information related to adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.

KEY POINTS TO CONSIDER

Data Quality

- There are many instances of duplicative reports and some reports do not contain all the necessary information.

Existence of a report does not establish causation

- There is no certainty that a suspected drug caused the adverse events.
- Adverse events may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons.
- The information in these reports reflects only the reporter's observations and opinions.

Information in reports has not been verified

- Submission of a report does not mean that the information included in it has been medically confirmed.

KEY POINTS TO CONSIDER

- ❑ **Rates of occurrence cannot be established with reports**
 - The number of adverse events should not be used to determine the likelihood of a side effect occurring.
 - Factors such as the time a product has been marketed and publicity can influence reporting.

- ❑ **Patients should talk to their doctor** before stopping or changing how they take their medications

- ❑ **Patient Outcomes received in FAERS**
 - A reported serious outcomes does not necessarily mean that the suspect product(s) named in the report was the cause of these outcomes.



FAERS data by themselves are not an indicator that the drug is causing the reported adverse events.

SPONTANEOUS REPORTS

- A communication from an individual (e.g., health care professional, consumer) to a company or regulatory authority
- Describes a suspected adverse event(s)
- Passive and voluntary reports

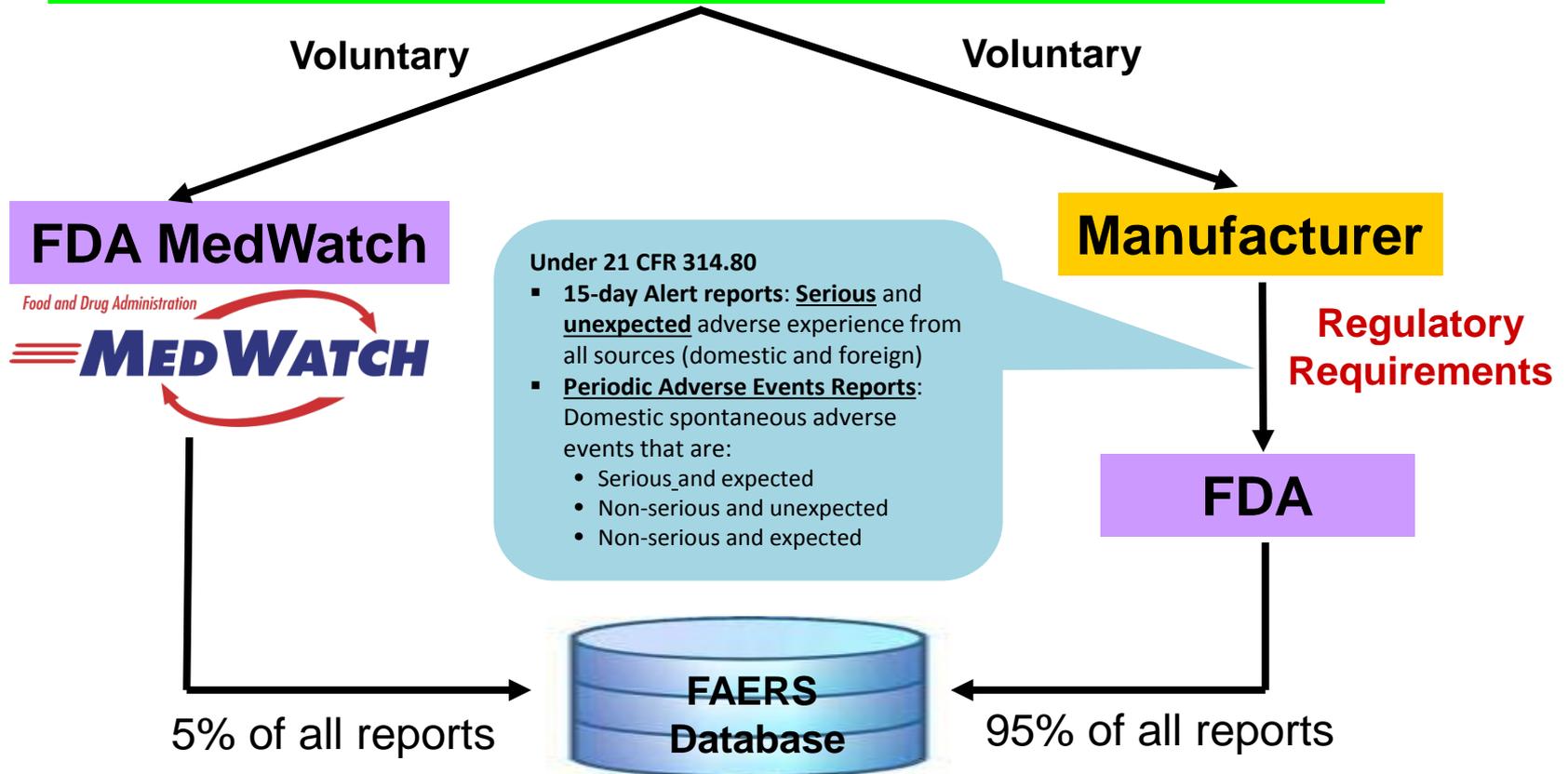
FACTORS AFFECTING REPORTING

- Media attention
- Litigation (class action lawsuits)
- Nature of the adverse event
- Type of drug product and indication
- Length of time on market
- Extent and quality of manufacturer's surveillance system
- Prescription or over-the-counter (OTC) product status
- Reporting regulations

HOW POSTMARKETING REPORTS GET TO FDA



Patients, consumer, and healthcare professionals



FAERS STRENGTHS

- ❑ Includes all U.S. marketed products
- ❑ Includes all uses
- ❑ Includes broad patient populations:
 - elderly, children, pregnant women, co-morbidities
- ❑ Especially good for events with a rare background rate
- ❑ Useful for events that occur shortly after exposure
- ❑ Detection of events not seen in clinical trials (“signal generation”)
- ❑ Identification of reporting trends, possible risk factors, at risk populations, and other clinically significant emerging safety concerns

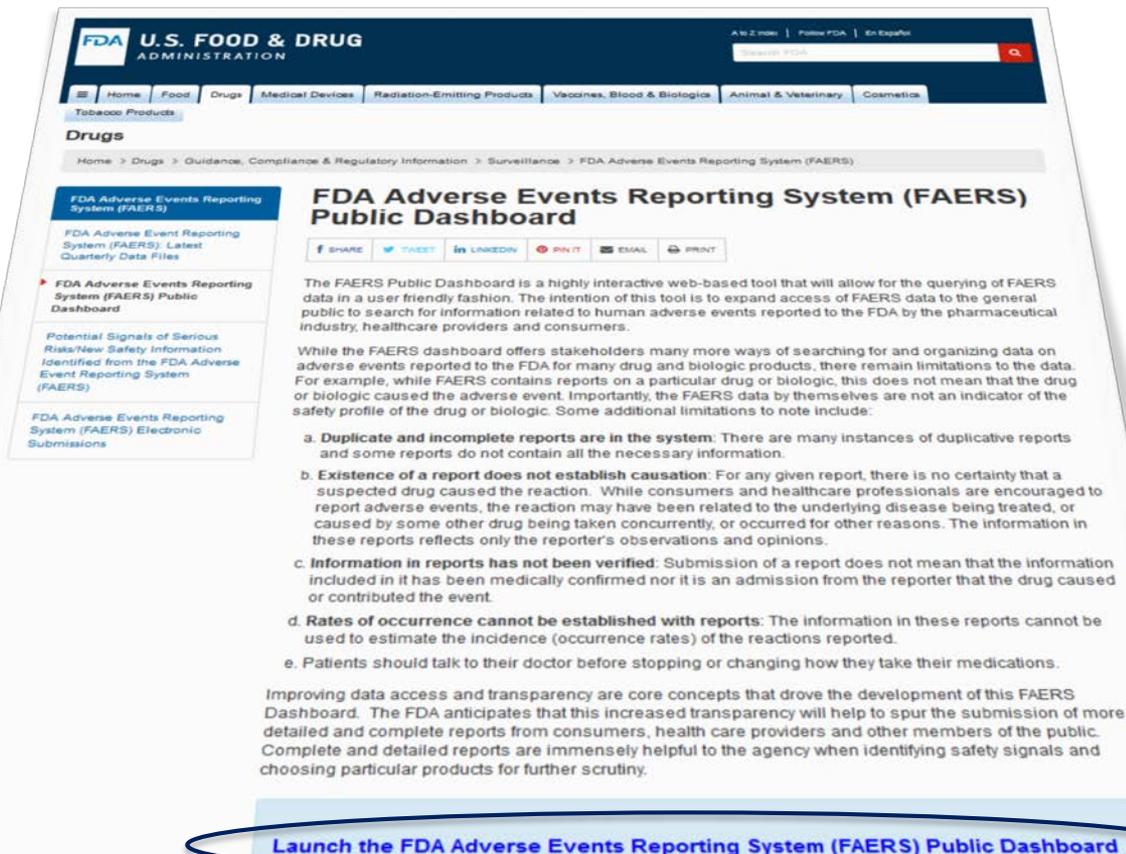
FAERS IS LESS USEFUL FOR

- Events with high background rates
- Worsening of pre-existing disease
- Issue that goes beyond data captured from the MedWatch Form or electronic reporting
- Comparative incidence rates
- Comparing drugs in the same class
- Adverse events that could also be manifestations of the disease for which the drug is indicated

FAERS PUBLIC DASHBOARD

LAUNCH FAERS PUBLIC DASHBOARD

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>



The screenshot shows the FDA Adverse Events Reporting System (FAERS) Public Dashboard. The page header includes the FDA logo and navigation links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, and Cosmetics. The main content area is titled "FDA Adverse Events Reporting System (FAERS) Public Dashboard" and includes a search bar, social media sharing options, and a list of links to related information. The dashboard text explains that the tool is highly interactive and allows for querying of FAERS data in a user-friendly fashion. It also lists several limitations of the data, such as duplicate and incomplete reports, unverified information, and the inability to establish rates of occurrence.

FDA Adverse Events Reporting System (FAERS) Public Dashboard

The FAERS Public Dashboard is a highly interactive web-based tool that will allow for the querying of FAERS data in a user friendly fashion. The intention of this tool is to expand access of FAERS data to the general public to search for information related to human adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.

While the FAERS dashboard offers stakeholders many more ways of searching for and organizing data on adverse events reported to the FDA for many drug and biologic products, there remain limitations to the data. For example, while FAERS contains reports on a particular drug or biologic, this does not mean that the drug or biologic caused the adverse event. Importantly, the FAERS data by themselves are not an indicator of the safety profile of the drug or biologic. Some additional limitations to note include:

- Duplicate and incomplete reports are in the system:** There are many instances of duplicative reports and some reports do not contain all the necessary information.
- Existence of a report does not establish causation:** For any given report, there is no certainty that a suspected drug caused the reaction. While consumers and healthcare professionals are encouraged to report adverse events, the reaction may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons. The information in these reports reflects only the reporter's observations and opinions.
- Information in reports has not been verified:** Submission of a report does not mean that the information included in it has been medically confirmed nor is it an admission from the reporter that the drug caused or contributed the event.
- Rates of occurrence cannot be established with reports:** The information in these reports cannot be used to estimate the incidence (occurrence rates) of the reactions reported.
- Patients should talk to their doctor before stopping or changing how they take their medications.

Improving data access and transparency are core concepts that drove the development of this FAERS Dashboard. The FDA anticipates that this increased transparency will help to spur the submission of more detailed and complete reports from consumers, health care providers and other members of the public. Complete and detailed reports are immensely helpful to the agency when identifying safety signals and choosing particular products for further scrutiny.

Launch the FDA Adverse Events Reporting System (FAERS) Public Dashboard

DISCLAIMER

Disclaimer

Each year, the FDA receives over one million adverse event and medication error reports associated with the use of drug or biologic products. The FDA uses these reports to monitor the safety of drug and biological products. The FDA Adverse Event Reporting System (FAERS) database houses reports submitted to the FDA by drug manufacturers (who are required to submit these reports to FDA) and others such as health care professionals and consumers. Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Although these reports are a valuable source of information, this surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified information. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of use. Because of this, FAERS data comprise only one part of the FDA's important post-market surveillance data and the information on this website does not confirm a causal relationship between the drug product and the reported adverse event(s).

- Consumers should not stop or change medication without first consulting with a health care professional.
- The FAERS web search feature is limited to adverse event reports between 1969 and the most recent quarter for which data are available.
- Data submitted to the FAERS system will be made available through the new querying tool on a quarterly basis.
- FAERS data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between drug products. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with drug products.
- Confirming whether a drug product actually caused a specific event can be difficult based solely on information provided in a given report.
- FAERS data do not represent all known safety information for a reported drug product and should be interpreted in the context of other available information when making drug-related or treatment decisions.
- Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.

Importantly, safety reports submitted to FDA do not necessarily reflect a conclusion by FDA that the information in the reports constitutes an admission that the drug caused or contributed to an adverse event. Individual FAERS reports for a given product can be requested by submitting a Freedom of Information Act (FOIA) request at:

<https://www.fda.gov/oc/regulatoryinformation/foi/howtomakeafoiarequest/default.htm>

Click on "Accept" to accept disclaimer and view information on the dashboard

QUESTION 1



Select all the key points to consider while viewing the contents of the dashboard

- a. Quality of adverse event data
- b. Existence of a report does not establish causation
- c. Information in reports has not been verified
- d. Rates of occurrence cannot be established with reports
- e. Patients should talk to their doctor before stopping or changing their medication
- f. All of the above

QUESTION 2



Dr. Doe a private physician views adverse event data on a product. Looking at the volume of the data set for that product he concludes that the product is risky to prescribe.

Did Dr. Doe make an informed decision?

- a. Yes
- b. No

QUESTION 2

Dr. Doe a private physician views adverse event data on a product. Looking at the volume of the data set for that product he concludes that the product is risky to prescribe.

Did Dr. Doe make an informed decision?

a. Yes

b. No

- Existence of a report does not establish causation
- Rates of occurrence cannot be established with reports

KEY PARTS OF DASHBOARD

Filter panel



Navigation panel

Main Dashboard Page

Provides an option to search adverse event by product

Home

Search for Products

View Disclaimer

Disclaimer

Site Feedback

Report a Problem

FAQ

Provide feedback on the dashboard

Report an adverse event via a web portal

Frequently Asked Questions

Count panel

Total Reports

14,199,191

Displays total number of reports as of a date

Serious Reports (excluding death)

8,072,400

Displays counts of all serious reports (excluding death reports)

Death Reports

1,420,085

Displays counts of all death reports

Reports by Report Type

View reports by different criterias

KEY PARTS OF DASHBOARD



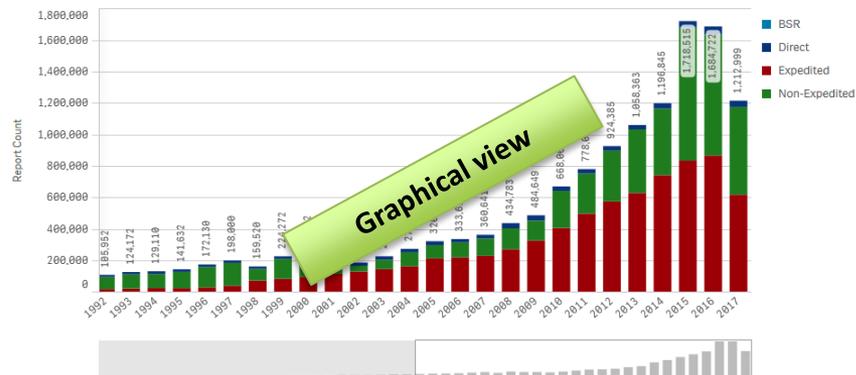
Data panel

Reports received by Year and Report Type

Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports	14,160,191	7,437,939	6,488,852	739,781	873
2017	1,212,999	615,558	508,052	40,383	-
2016	1,684,722	864,309	720,393	50,879	-
2015	1,718,515	831,111	887,404	41,539	-
2014	1,196,845	599,052	597,793	34,114	-
2013	1,058,363	539,052	519,311	28,303	-
2012	924,385	464,586	460,000	28,866	-
2011	778,649	394,961	381,000	27,995	-
2010	668,000	404,586	263,914	28,902	-
2009	484,649	324,421	160,228	34,099	-
2008	434,783	269,298	165,485	32,826	-
2007	360,641	227,294	133,600	22,958	-
2006	333,629	217,213	116,512	20,891	-
2005	320,016	210,363	109,000	25,175	6
2004	271,418	160,008	98,000	21,572	5
2003	234,344	143,750	80,000	23,070	4

Tabular view

Reports received by Year and Report Type



Graphical view

Page help panel

This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.

- Direct Reports are voluntarily submitted directly to FDA through the MedWatch program by consumers and healthcare professionals.
- Mandatory Reports are submitted by manufacturers and are categorized as:
 - Expedited reports that contain at least one adverse event that is not currently described in the product labeling and for which the patient outcome is serious, or
 - Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.

Describes the details of data displayed on the page

MAIN DASHBOARD PAGE



Main Dashboard Page

Selected filter criteria

Provides an option to search adverse event by product

Provide feedback on the dashboard

Report an adverse event via a web portal

Frequently Asked Questions

Displays counts of all death reports

View Disclaimer



Home Search for Products Disclaimer Site Feedback Report a Problem FAQ

Total Reports
14,160,191

Serious Reports (excluding death)
8,072,400

Death Reports
1,420,885

Reports by Report Type

Displays total number of reports as of a date

Displays counts of all serious reports (excluding death reports)

View reports by different criteria

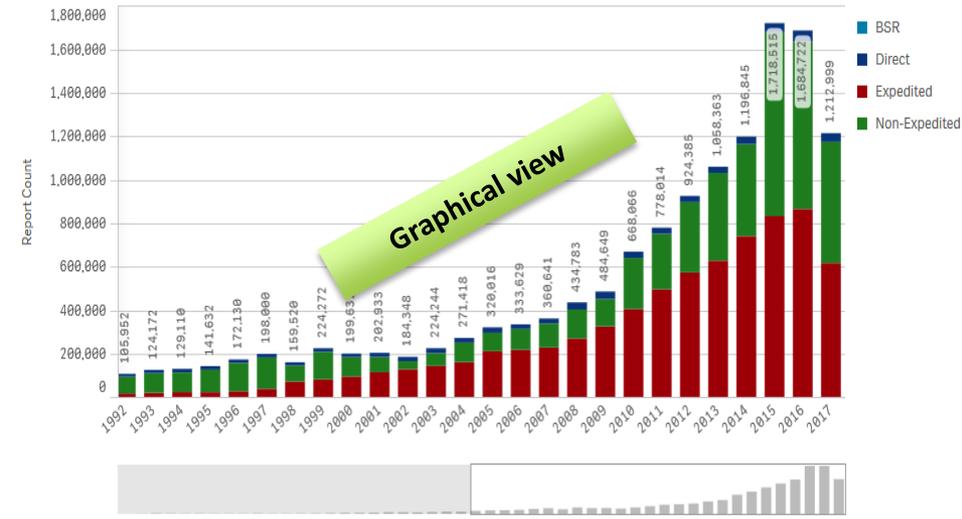
Since 1968 Last 10 Years

Reports received by Year and Report Type

Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports	14,160,191	7,437,939	5,981,598	739,781	873
2017	1,212,999	615,558	557,058	40,383	-
2016	1,684,722	864,309	769,534	50,879	-
2015	1,718,515	831,924	745,052	41,539	-
2014	1,196,845	739,581	457,150	34,114	-
2013	1,058,363	626,697	431,368	28,303	-
2012	924,385	514,586	323,059	28,866	-
2011	778,014	414,586	255,058	27,995	-
2010	668,066	324,421	234,578	28,902	-
2009	484,649	324,421	126,138	34,090	-
2008	434,783	269,298	132,659	32,826	-
2007	360,641	227,294	110,389	22,958	-
2006	333,629	217,213	95,525	20,891	-
2005	320,016	210,363	84,472	25,175	6
2004	271,418	160,008	89,833	21,572	5
2003	224,244	142,750	59,601	22,970	14

Tabular view

Reports received by Year and Report Type



Data as of August 31, 2017

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- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.

Describes the details of data displayed on the page

MAIN DASHBOARD

REPORTS BY REPORT TYPE

Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by report type

Home Search for Products
Disclaimer Site Feedback Report a Problem FAQ

Total Reports
14,160,191

Serious Reports (excluding death)
8,072,400

Death Reports
1,420,885

Reports by Report Type

Since 1968 Last 10 Years

Reports received by Year and Report Type

Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
2015	1,718,515	831,974	845,052	41,539	
2014	1,196,845	739,581	423,150	34,114	
2013	1,058,363	626,692	403,368	28,303	
2012	924,385	572,460	323,059	28,866	
2011	778,814	494,961	255,058	27,995	
2010	668,066	484,586	234,578	28,902	
2009	484,649	324,421	176,138	34,990	
2008	434,783	269,298	132,659	32,826	
2007	360,641	227,294	110,389	22,958	
2006	333,629	217,213	95,525	20,891	
2005	320,016	210,363	84,472	25,175	6
2004	271,418	168,008	89,833	21,572	5
2003	224,244	142,759	58,601	22,878	14
2002	184,348	127,392	36,558	20,377	21
2001	202,933	113,476	78,162	19,243	52
2000	199,632	94,051	89,140	16,085	350
1999	224,272	88,889	127,050	16,161	172

Reports received by Year and Report Type

Info as of August 31, 2017

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MAIN DASHBOARD

REPORTS BY REPORTER

Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by type of reporter

Home
Disclaimer Site Feedback Report a Problem FAQ

Total Reports
↑ 10,161,341

Serious Reports (excluding death)
⚠ 5,450,852

Death Reports
✖ 1,041,037

Reports by Reporter

Since 1968 Last 18 Years

Reports received by Year and Reporter

Year
Category

	Total Reports	Healthcare Professional	Consumer	Other	Not Specified
Total Reports	10,161,341	4,942,447	4,930,222	5	288,667
2017	1,212,999	638,447	577,428	-	5,132
2016	1,684,722	831,414	845,355	-	7,953
2015	1,718,515	769,581	934,812	-	13,922
2014	1,196,845	573,618	603,268	-	19,969
2013	1,058,363	543,877	496,532	1	17,953
2012	924,385	462,967	435,821	4	26,393
2011	778,014	378,982	361,873	-	38,859
2010	668,066	388,173	386,914	-	52,979
2009	484,649	235,345	195,378	-	53,926
2008	434,783	207,725	174,657	-	52,401

Reports received by Year and Reporter

Year	Healthcare Professional	Consumer	Other	Not Specified
2008	207,725	174,657	-	52,401
2009	235,345	195,378	-	53,926
2010	388,173	386,914	-	52,979
2011	378,982	361,873	-	38,859
2012	462,967	435,821	4	26,393
2013	543,877	496,532	1	17,953
2014	573,618	603,268	-	19,969
2015	769,581	934,812	-	13,922
2016	831,414	845,355	-	7,953
2017	638,447	577,428	-	5,132

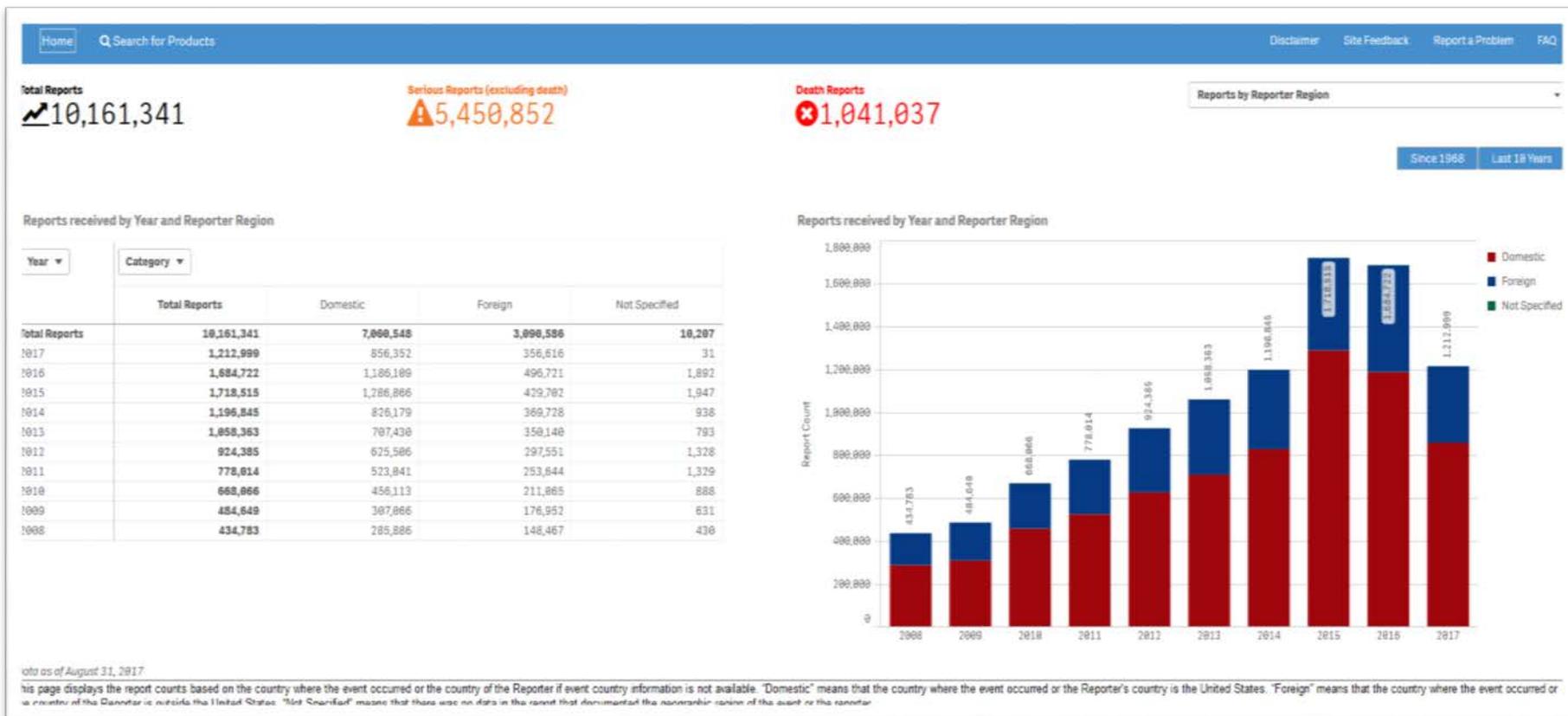
data as of August 31, 2017

This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports to FDA most frequently. Additional HCPs include nurses, dentists and other medical personnel. Reporters may also be classified as "Consumer", "Other" for all other Reporters who are not documented as Healthcare Professionals or Consumers, and "Not Specified" where the occupation of the Reporter was not provided.

MAIN DASHBOARD

REPORTS BY REPORTER REGION

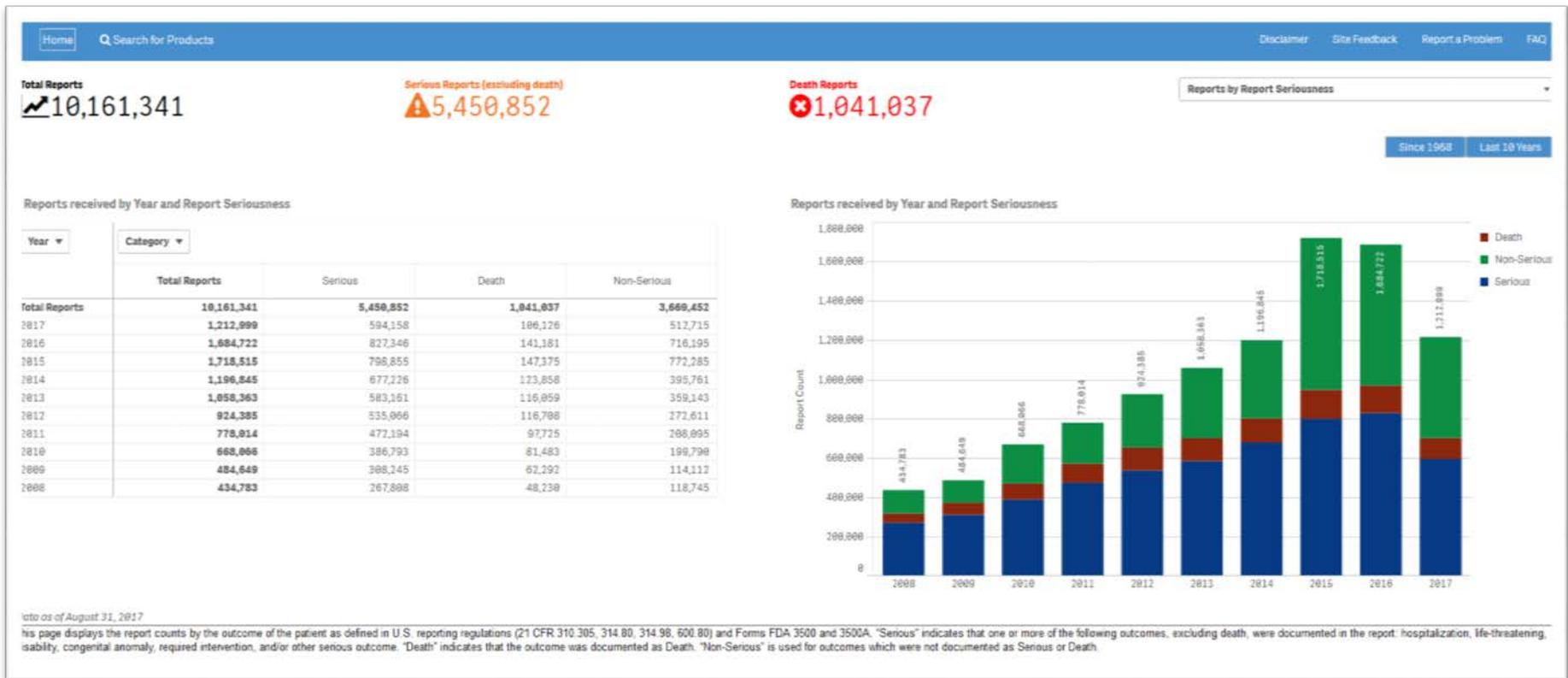
Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic based on the country where the event occurred.



MAIN DASHBOARD

REPORTS BY REPORT SERIOUSNESS

Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by outcome of the patient as defined in regulations (21CFR 310.305, 314.80, 314.98, 600.80) and FDA MedWatch forms (3500 and 3500B)





QUESTION 3

The report counts on the main dashboard page are the counts of reports that include initials and follow-ups

- a. True
- b. False

QUESTION 4

The main dashboard page displays report counts on which of the following criteria

- a. Report Type
- b. Reporter
- c. Reporter Region
- d. Report Seriousness
- e. All of the above



SEARCH FOR PRODUCTS

SEARCH FOR PRODUCTS



Search for products

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Search for Products Disclaimer Site Feedback Report a Problem FAQ

Total Reports 14,160,191

Serious Reports (excluding death) 8,072,400

Death Reports 1,420,885

Reports by Report Type: Since 1968 Last 10 Years

Reports received by Year and Report Type

Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
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2014	1,196,845	739,581	423,150	34,114	-
2013	1,058,363	626,692	403,368	28,303	-
2012	924,385	572,469	323,059	28,966	-
2011	778,014	494,961	255,058	27,995	-
2010	668,066	484,586	234,578	28,992	-
2009	484,649	324,421	126,138	34,099	-
2008	434,783	269,298	132,659	32,826	-
2007	368,641	227,294	118,389	22,958	-
2006	333,629	217,213	95,525	20,891	-
2005	320,816	210,363	84,472	25,175	6
2004	271,418	168,088	89,833	21,572	5
2003	224,244	142,759	58,801	22,879	14
2002	184,348	127,392	36,558	20,377	21

Data as of August 31, 2017

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- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.

Reports received by Year and Report Type

SEARCH FOR PRODUCTS



A screenshot of the FDA Adverse Events Reporting System (FAERS) Public Dashboard. The page has a dark grey header with "No selections applied" on the left and the FDA logo on the right. Below the header is a blue navigation bar with "Home" and "Search for Products" (with a magnifying glass icon) on the left, and "Disclaimer", "Site Feedback", "Report a Problem", and "FAQ" on the right. The main content area is white and features a search section titled "Search for a Product" above a search input field. A green callout box with a white border and a shadow points to the search input field. The callout box contains the text: "Search for a product (brand name) or active ingredient (generic name). This field provides a smart search capability".

Search for a product (brand name) or active ingredient (generic name). This field provides a smart search capability

SEARCH FOR PRODUCTS

FAERS Public Dashboard

Home Disclaimer Site Feedback Report a Problem FAQ

Field to search for both brand name and generic name products. Typing three letters provides all match texts highlighted in yellow.

Search for a Product

ami	
Amlodipine	G
Amlodipine	P
Amlodipine And Atorvastatin	P
Amlodipine And Olmesartan Medoxomil	P
Amlodipine And Valsartan	P
Amlodipine Besylate	G
Amlodipine Besylate And Atorvastatin Calcium	P
Amlodipine Besylate And Benazepril Hydrochloride	P
Amlodipine Besylate And Valsartan	P
Amlodipine Besylate/Atorvastatin Calcium	P

Select "Amlodipine Besylate"

P (in green color) – Brand Name of the product

G (in orange color) – Generic Name of the product

QUESTIONS 5

Rebecca is a researcher at a university and is currently researching on a recently approved drug with NDA number 209310 (i.e. SINUVA – brand name, MOMETASONE FUROATE – generic name). She is exploring FAERS public dashboard to find information on the product of interest.

Select the applicable options for her to perform a search for product details?

- a. By NDA number
- b. By Brand Name
- c. By Generic Name
- d. By Brand Name or Generic Name
- e. None of the above

SEARCH PRODUCT RESULT



Filter applied for the selected product

Total number of latest version of the reports listed

AMLODIPINE BESYLATE

Selected product displayed

List of reports available

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases

Disclaimer Site Feedback Report a Problem FAQ

Search Term: Amlodipine Besylate

Total Cases: 47,204

Serious Cases (including deaths): 41,047

Death Cases: 6,608

Case Count by Received Year

Category	Number of Cases	Percentage
2017	3,352	7.10%
2016	4,074	8.63%
2015	3,721	7.88%
2014	3,333	7.06%
2013	3,496	7.41%
2012	2,553	5.41%
2011	2,342	4.96%
2010	2,318	4.91%
2009	1,323	2.80%
2008	961	2.04%
2007	1,021	2.16%
2006	930	1.97%
2005	892	1.89%
Totals	47,204	100.00%

Case Count by Received Year (Bar Chart)

2017: 3,352
2016: 4,074
2015: 3,721
2014: 3,333
2013: 3,496
2012: 2,553
2011: 2,342
2010: 2,318
2009: 1,323
2008: 961
2007: 1,021
2006: 930
2005: 892

Menu: Cases by Received Year, Cases by Reaction, Cases by Age Group, Cases by Sex, Cases by Reporter Type

Date as of August 31, 2017

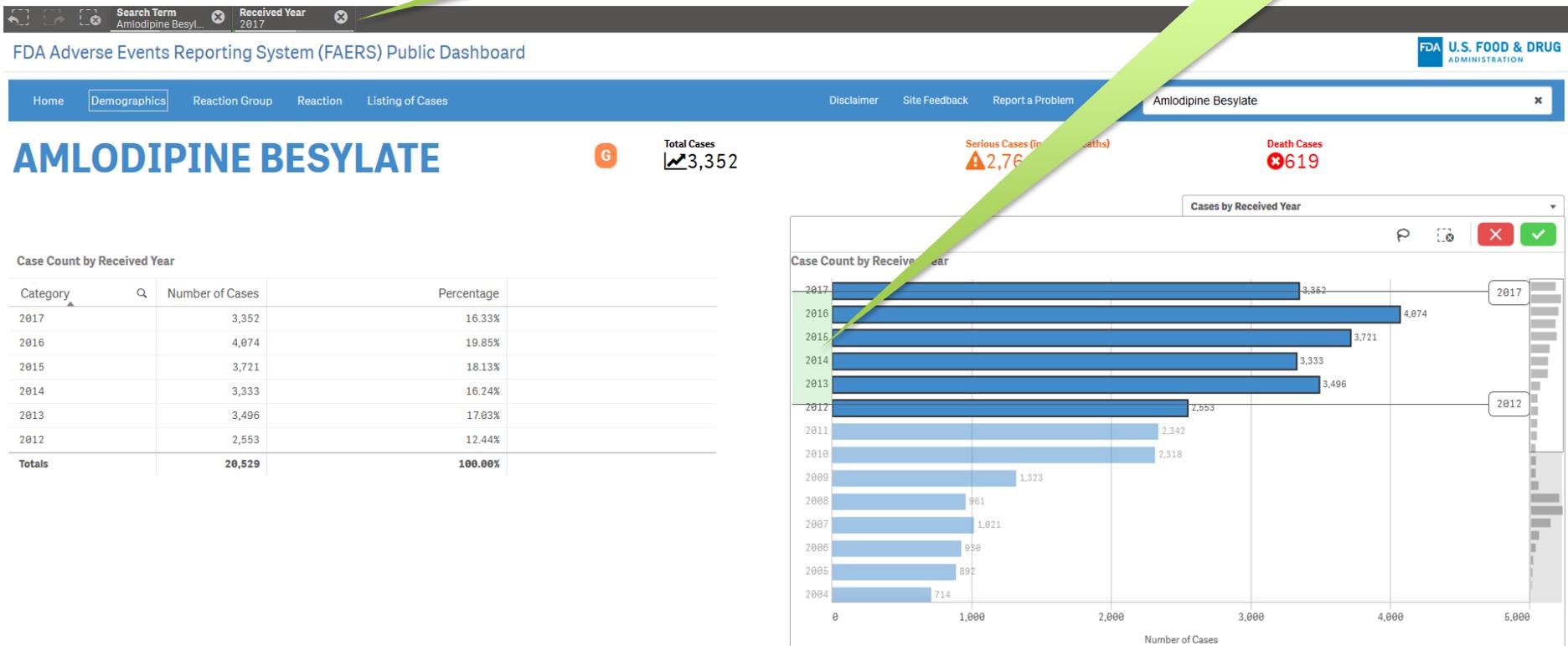
This page displays the number of cases identified for the product of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

DEMOGRAPHICS



Filters applied for years

Drag the mouse to select years or by individual clicks



Data as of August 31, 2017
 This page displays the number of cases identified for the product of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Search Term: Amlodipine Besylate | Received Year: 6 of 58

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home | Demographics | Reaction Group | Reaction | Listing of Cases

Disclaimer | Site Feedback | Report a Problem | FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 20,529

Serious Cases (including deaths) 16,459

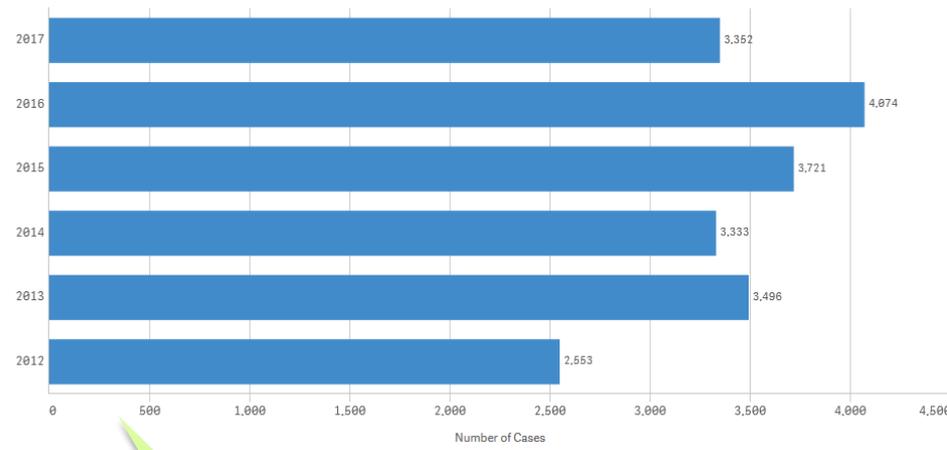
Death Cases 3,146

Cases by Received Year

Case Count by Received Year

Category	Number of Cases	Percentage
2017	3,352	16.33%
2016	4,074	19.85%
2015	3,721	18.13%
2014	3,333	16.24%
2013	3,496	17.03%
2012	2,553	12.44%
Totals	20,529	100.00%

Case Count by Received Year



Data as of August 2017. This page displays the number of cases identified for the product of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

Case by years - tabular view

Case by years - graphical view

DEMOGRAPHICS



Search Term: Amlodipine Besylate Received Year: 6 of 50

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases

Disclaimer Site Feedback Report a Problem FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases: 20,529

Serious Cases (including deaths): 16,459

Death Cases: 3,146

Cases by Reaction

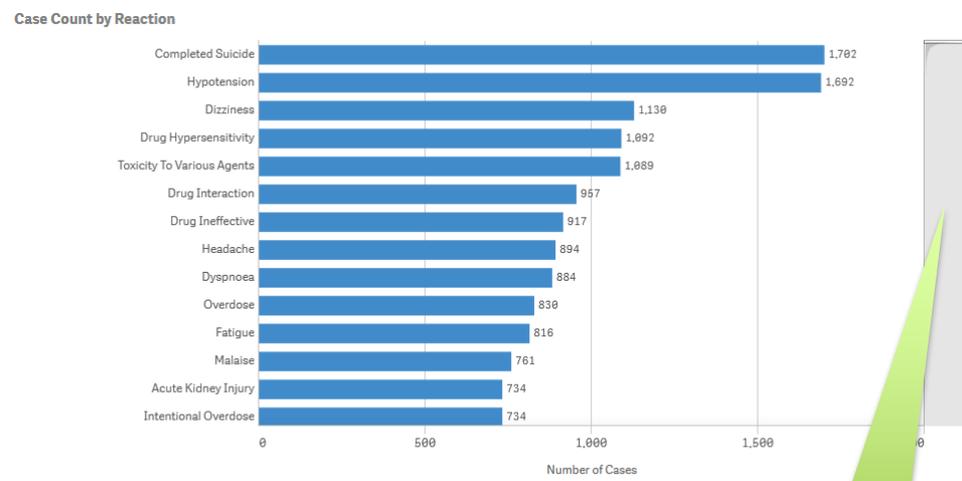
Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Reactions

Case Count by Reaction

Category	Number of Cases	Percentage
Completed Suicide	1,702	8.29%
Hypotension	1,692	8.24%
Dizziness	1,130	5.50%
Drug Hypersensitivity	1,092	5.32%
Toxicity To Various Agents	1,089	5.30%
Drug Interaction	957	4.66%
Drug Ineffective	917	4.47%
Headache	894	4.35%
Dyspnoea	884	4.31%
Overdose	830	4.04%
Fatigue	816	3.97%
Malaise	761	3.71%
Acute Kidney Injury	734	3.58%
Totals	20,529	100.00%



Reactions listed in descending order

Scrollbar to view all reactions

Data as of August 31, 2017

This page displays the number of cases reported for the product of interest by "Reaction". "Reaction" is the suspected side effect (also known as adverse event or adverse drug reaction) reported by the reporter and is based on the MedDRA dictionary Preferred Term (PT). A "Reaction" is a unique medical condition, symptom, sign, disease, diagnosis, therapeutic indication, investigation, surgical or medical procedure, etc. A case may contain more than one "Reaction".

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Age Group

Search Term: Amlodipine Besylate | Received Year: 6 of 50

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home | Demographics | Reaction Group | Reaction | Listing of Cases

Disclaimer | Site Feedback | Report a Problem | FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 20,529

Serious Cases (including deaths) 16,459

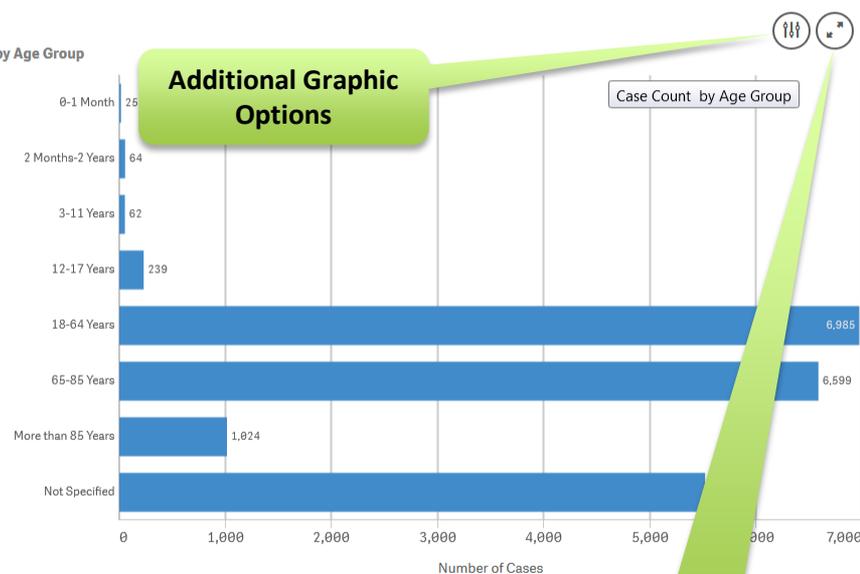
Death Cases 3,146

Cases by Age Group

Case Count by Age Group

Category	Number of Cases	Percentage
0-1 Month	25	0.12%
2 Months-2 Years	64	0.31%
3-11 Years	62	0.30%
12-17 Years	239	1.16%
18-64 Years	6,985	34.03%
65-85 Years	6,599	32.14%
More than 85 Years	1,024	4.99%
Not Specified	5,531	26.94%
Totals	20,529	100.00%

Case Count by Age Group



Additional Graphic Options

Click to expand the view

Data as of August 31, 2017
 This page displays the number of cases identified for the product of interest by the reported age of the patient. "Not Specified" indicates the patient's age was not reported.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Sex

Search Term: Amlodipine Besylate | Received Year: 6 of 50

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home | Demographics | Reaction Group | Reaction | Listing of Cases

Disclaimer | Site Feedback | Report a Problem | FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE

G Total Cases 20,529

Serious Cases (including deaths) 16,459

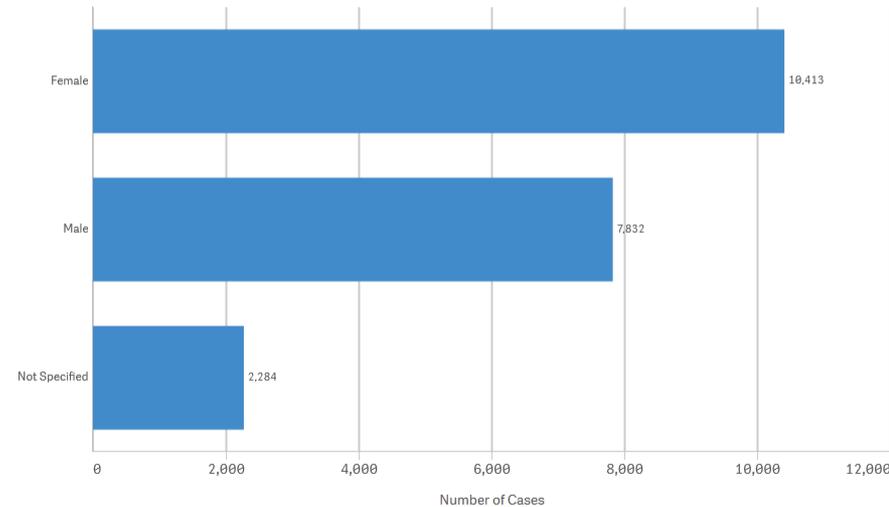
Death Cases 3,146

Cases by Sex

Case Count by Sex

Category	Number of Cases	Percentage
Female	10,413	50.72%
Male	7,832	38.15%
Not Specified	2,284	11.13%
Totals	20,529	100.00%

Case Count by Sex



Data as of August 31, 2017
 This page displays the number of cases identified for the product of interest by sex. "Not Specified" indicates the patient's sex was not reported.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Reporter Type

Search Term: Amlodipine Besylate Received Year: 6 of 50

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE



Total Cases 20,529

Serious Cases (including deaths) 16,459

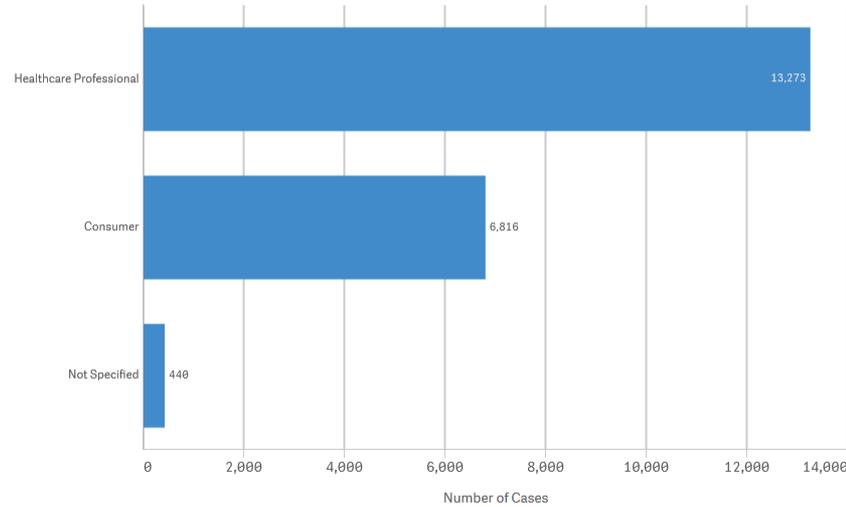
Death Cases 3,146

Cases by Reporter Type

Case Count by Reporter

Category	Number of Cases	Percentage
Healthcare Professional	13,273	64.65%
Consumer	6,816	33.20%
Not Specified	440	2.14%
Totals	20,529	100.00%

Case Count by Reporter



Data as of August 31, 2017

This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports to FDA most frequently. Additional HCPs include nurses, dentists and other medical personnel. Reporters may also be classified as "Consumer", "Other" for all other Reporters who are not documented as Healthcare Professionals or Consumers, and "Not Specified" where the occupation of the Reporter was not provided.

DEMOGRAPHICS



Reporter type filter
"Healthcare
Professional" applied

Cases by Reporter
Type

Search Term: Amlodipine Besylate | Received Year: 6 of 50 | Reporter Type: Healthcare Professional

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home | Demographics | Reaction Group | Reaction | Listing of Cases

Disclaimer | Site Feedback | Report a Problem | FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 13,273

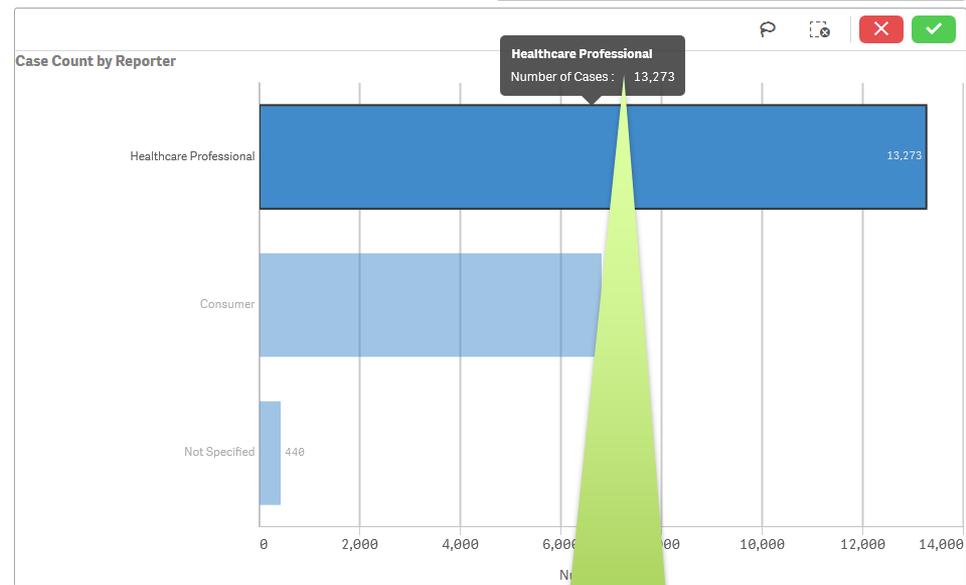
Serious Cases (including deaths) 11,784

Death Cases 2,739

Cases by Reporter Type

Case Count by Reporter

Category	Number of Cases	Percentage
Healthcare Professional	13,273	100.00%
Totals	13,273	100.00%



Data as of August 31, 2017

This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports to FDA most frequently. Additional HCPs include nurses, dentists and other medical personnel. Reporters may also be classified as "Consumer", "Not Specified", or "Other" where the Reporter was not provided.

Total number of cases based on applied filter

Hover over to view information

QUESTIONS 6

Rebecca is looking for the information about “Amlodipine Besylate” from 2012 to 2017 and reports from healthcare professional only. Then she decides to look for the reaction hypotension. How many steps does Rebecca need to get her results?

- a. 5
- b. 3
- c. 2
- d. 4

QUESTIONS 6

Rebecca is looking for the information about “Amlodipine Besylate” from 2012 to 2017 and reports from healthcare professional only. Then she decides to look for reaction related to hypotension. How many steps Rebecca need to perform to reach to her results?

- a. 5
- b. 3
- c. 2
- d. 4

Step 1: Select product (Amlodipine Besylate)

Step 2: Select Years (2012 to 2017)

Step 3: Select Reporter Type (healthcare professional)

Step 4: Click on reaction (hypotension)

QUESTIONS 7

Rebecca has applied the age groups 12-17 years and 18-64 in the previous exercise. Now she decides to remove the healthcare professional filter.

What is the best option to remove the healthcare professional filter?

- a. Deselect from "Cases by Reporter Type" page
- b. Unselect Reporter Type from filter section on top
- c. Resetting entire filters
- d. Start a new search

QUESTIONS 8

Rebecca is confused with the information provided in “Case by Sex” as “Not Specified.” While examining the information she asked a question to helpdesk about details of “Not Specified.”

What is the best answer helpdesk can provide?

- a. Sex is reported as unknown
- b. Transgender
- c. Missing gender information
- d. Sex was not reported

QUESTIONS 8

Rebecca is confused with the information provided in “Case by Sex” as “Not Specified.” While examining the information she asked the helpdesk a question about details of “Not Specified.”

What is the best answer the helpdesk can provide?

- a. Sex is reported as unknown
- b. Transgenders
- c. Missing gender information
- d. Sex was not reported

“Not Specified” indicates the patient’s sex was not reported as these reports are voluntary.

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Age Group

Search Term: Amlodipine Besylate | Received Year: 6 of 50 | Reporter Type: Healthcare Professional | Age Group: 2 of 8

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home | Demographics | **Reaction Group** | Reaction | Listing of Cases

Disclaimer | Site Feedback | Report a Problem | FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases **5,325**

Serious Cases (including deaths) **4,952**

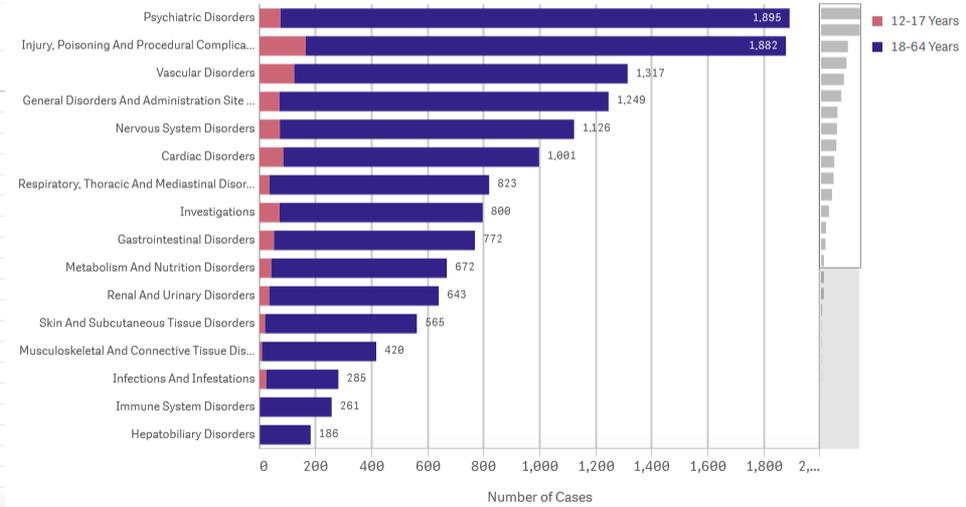
Death Cases **1,554**

Cases by Age Group

Reaction Groups & Age Group

Reaction Group	Number of Cases	12-17 Years	18-64 Years
Total Cases	5,325	228	5,097
Psychiatric Disorders	1,895	78	1,817
Injury, Poisoning And Procedural Complications	1,882	168	1,714
Vascular Disorders	1,317	127	1,190
General Disorders And Administration Site Conditions	1,249	74	1,175
Nervous System Disorders	1,126	76	1,050
Cardiac Disorders	1,001	88	913
Respiratory, Thoracic And Mediastinal Disorders	823	39	784
Investigations	800	75	725
Gastrointestinal Disorders	772	55	717
Metabolism And Nutrition Disorders	672	45	627
Renal And Urinary Disorders	643	38	605
Skin And Subcutaneous Tissue Disorders	565	23	542
Musculoskeletal And Connective Tissue Disorders	420	12	408
Infections And Infestations	285	27	258
Immune System Disorders	261	5	256
Hepatobiliary Disorders	186	5	181
Eye Disorders	186	5	181
Blood And Lymphatic System Disorders	180	13	167
Surgical And Medical Procedures	98	8	90

Reaction Groups & Age Group



Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Sex

Search Term: Amlodipine Besylate | Received Year: 6 of 50 | Reporter Type: Healthcare Professional | Age Group: 2 of 8

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home | Demographics | **Reaction Group** | Reaction | Listing of Cases

Disclaimer | Site Feedback | Report a Problem | FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE

G Total Cases 5,325

4,952 Serious Cases (including deaths)

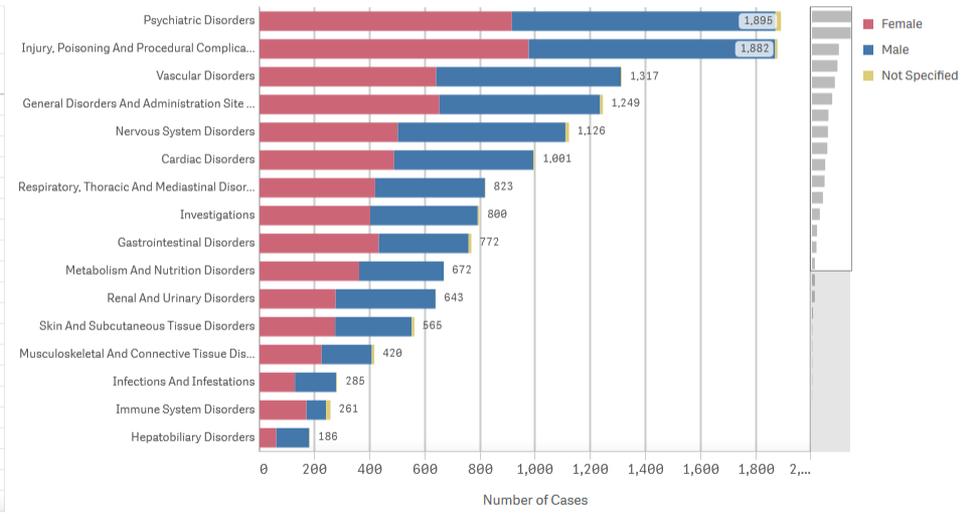
1,554 Death Cases

Cases by Sex

Reaction Groups & Sex

Reaction Group	Number of Cases	Male	Not Specified	Female
Total Cases	5,325	2,660	63	2,602
Psychiatric Disorders	1,895	956	20	919
Injury, Poisoning And Procedural Complications	1,882	894	8	980
Vascular Disorders	1,317	670	3	644
General Disorders And Administration Site Conditions	1,249	583	10	656
Nervous System Disorders	1,126	608	13	505
Cardiac Disorders	1,001	505	4	492
Respiratory, Thoracic And Mediastinal Disorders	823	398	2	423
Investigations	800	390	5	405
Gastrointestinal Disorders	772	326	10	436
Metabolism And Nutrition Disorders	672	307	-	365
Renal And Urinary Disorders	643	362	1	280
Skin And Subcutaneous Tissue Disorders	565	277	10	278
Musculoskeletal And Connective Tissue Disorders	420	182	9	229
Infections And Infestations	285	150	3	132
Immune System Disorders	261	71	16	174
Hepatobiliary Disorders	186	120	2	64
Eye Disorders	186	77	-	109
Blood And Lymphatic System Disorders	180	103	-	77
Surgical And Medical Procedures	98	44	-	54

Reaction Groups & Sex



Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

REACTION GROUP



Age group filter applied

Additional filter capabilities for Reporter Type

Cases by Reporter Type

Total number of cases based on applied filter

FDA Adverse Events Reporting Dashboard

Search Term: Amlodipine Besyl... Received Year: 2017 Reporter Type: Healthcare Professional Age Group: 2 of 8

AMLODIPINE

Total Cases: 5,325

Serious Cases (including deaths): 4,952

Death Cases: 1,554

Reaction Groups & Reporter Type

Reaction Group	Number of Cases	Healthcare Professional
Total Cases	5,325	5,325
Psychiatric Disorders	1,895	1,895
Injury, Poisoning And Procedural Complications	1,882	1,882
Vascular Disorders	1,317	1,317
General Disorders And Administration Site Conditions	1,249	1,249
Nervous System Disorders	1,126	1,126
Cardiac Disorders	1,001	1,001
Respiratory, Thoracic And Mediastinal Disorders	823	823
Investigations	800	800
Gastrointestinal Disorders	772	772
Metabolism And Nutrition Disorders	672	672
Renal And Urinary Disorders	643	643
Skin And Subcutaneous Tissue Disorders	565	565
Musculoskeletal And Connective Tissue Disorders	420	420
Infections And Infestations	285	285
Immune System Disorders	261	261
Hepatobiliary Disorders	186	186
Eye Disorders	186	186
Blood And Lymphatic System Disorders	180	180
Surgical And Medical Procedures	98	98

Reaction Groups & Reporter Type

Number of Cases

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Reporter Region

Search Term: Amlodipine Besylate | Received Year: 6 of 50 | Reporter Type: Healthcare Professional | Age Group: 2 of 8

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home | Demographics | **Reaction Group** | Reaction | Listing of Cases

Disclaimer | Site Feedback | Report a Problem | FAQ

Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 5,325

Serious Cases (including deaths) 4,952

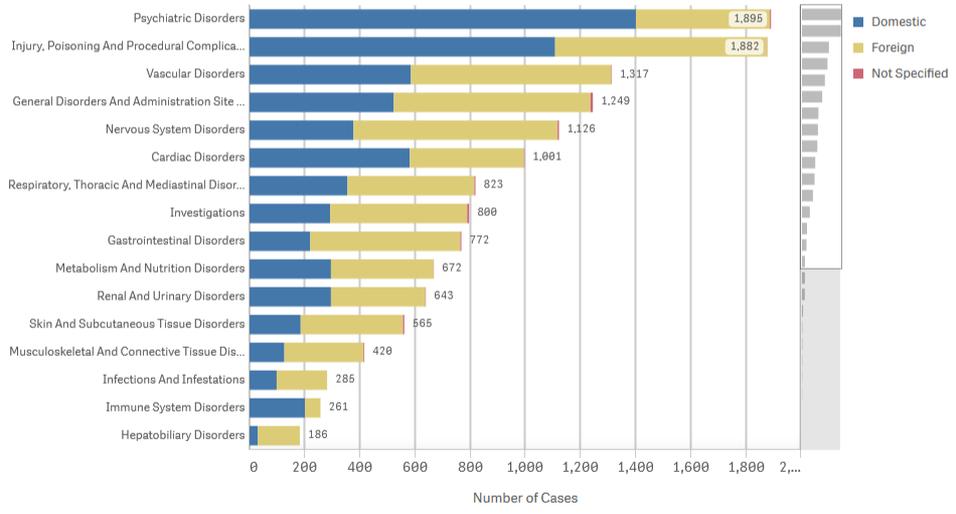
Death Cases 1,554

Cases by Reporter Region

Reaction Groups & Reporter Region

Reaction Group	Number of Cases	Domestic	Foreign	Not Specified
Total Cases	5,325	2,682	2,626	17
Psychiatric Disorders	1,895	1,405	486	4
Injury, Poisoning And Procedural Complications	1,882	1,112	769	1
Vascular Disorders	1,317	589	726	2
General Disorders And Administration Site Conditions	1,249	527	713	9
Nervous System Disorders	1,126	381	740	5
Cardiac Disorders	1,001	585	414	2
Respiratory, Thoracic And Mediastinal Disorders	823	359	460	4
Investigations	800	296	497	7
Gastrointestinal Disorders	772	224	544	4
Metabolism And Nutrition Disorders	672	299	372	1
Renal And Urinary Disorders	643	299	342	2
Skin And Subcutaneous Tissue Disorders	565	189	371	5
Musculoskeletal And Connective Tissue Disorders	420	130	287	3
Infections And Infestations	285	102	183	-
Immune System Disorders	261	205	56	-
Hepatobiliary Disorders	186	34	152	-
Eye Disorders	186	35	148	3
Blood And Lymphatic System Disorders	180	27	153	-
Surgical And Medical Procedures	98	47	49	2

Reaction Groups & Reporter Region



Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

QUESTIONS 9

Rebecca has extended her search and now she wants to view the information for only domestic cases and under nervous system disorders.

Which selections steps are the best to get quickly to results?

- a. Click on graph view and select “Nervous System Disorders” and “Domestic”
- b. Click on table view and select “Nervous System Disorders” and “Domestic”
- c. a or b

REACTION



Cases by Reaction Year vs Outcomes

Total number of cases based on applied filter

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group **Reaction** Listing of Cases

Disclaimer Site Feedback Report a Problem FAQ Amiodipine Besylate

AMLODIPINE BESYLATE

Total Cases **589**

Serious Cases (including deaths) **567**

Death Cases **59**

Received Year vs Outcome

Received Year vs Outcome

Age Group vs Sex

Reaction Group and Reaction

Reaction Group Reaction

Total Cases	Number of Cases
589	589
589	589
345	345
198	198
34	34
20	20
16	16
14	14
13	13
9	9
8	8
7	7
7	7
6	6
4	4
3	3
3	3
3	3
3	3

Outcome counts by Received Year and Outcome

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group", "Reaction", patient age and sex, and report outcome. A case may describe one or more "Reaction Group", "Reaction", or outcome. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". "Reaction" corresponds to the suspected reaction reported by the Reporter. The "Reaction" is based on the MedDRA dictionary Preferred Term (PT). Including one or more of these outcomes or reported reactions in a report does not necessarily mean that the suspect product of interest was the cause of the reported outcomes or reactions. A case may have one or more reported outcomes.

REACTION



Cases by Age Group vs Sex

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group **Reaction** Listing of Cases

Disclaimer Site Feedback Report a Problem FAQ

AMLODIPINE BESYLATE

Total Cases **589** Serious Cases (including deaths) **567** Death Cases **59**

Age Group vs Sex
Received Year vs Outcome
Age Group vs Sex

Reaction Group and Reaction

Reaction Group ▼ Reaction ▼

Total Cases	Number of Cases
589	589
	Vascular Disorders
	Hypotension
	Shock
	Hypertension
	Haemodynamic Instability
	Circulatory Collapse
	Blood Pressure Inadequately Controlled
	Orthostatic Hypotension
	Hypertensive Crisis
	Hyperperfusion
	Shock Haemorrhagic
	Distributive Shock
	Essential Hypertension
	Vasodilatation
	Haemorrhage
	Deep Vein Thrombosis
	Flushing
	Peripheral Ischaemia

Case counts by Age Group and Sex

Legend: Female (Red), Male (Blue), Not Specified (Grey)

Displayed by Reaction Group and Reaction

Dot as of August 31, 2017

This page displays the number of cases identified for a product of interest by "Reaction Group", "Reaction", patient age and sex, and report outcome. A case may describe one or more "Reaction Group", "Reaction", or outcome. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". "Reaction" corresponds to the suspected reaction reported by the Reporter. The "Reaction" is defined by the MedDRA dictionary Preferred Term (PT). Including one or more of these outcomes or reported reactions in a report does not necessarily mean that the suspect product of interest was the cause of the reported outcomes or reactions. A case may have one or more reported outcomes.

QUESTIONS 10

Rebecca was reviewing the chart “Reaction Year vs Outcome”. She noticed that cases have one or more outcomes. Is this correct that one case can have one or more reported outcomes?

- a. Yes
- b. No

QUESTIONS 11

Rebecca has found 3 cases on “Deep Vein Thrombosis” from product search “Amlodipine Besylate.” Does she has enough information to determine that “Amlodipine Besylate” cause the reaction “Deep Vein Thrombosis?” Choose the best answer.

- a. “Amlodipine Besylate” caused serious “Deep Vein Thrombosis” reaction
- b. “Amlodipine Besylate” did not cause serious “Deep Vein Thrombosis” reaction
- c. “Amlodipine Besylate” may have caused “Deep Vein Thrombosis” reaction
- d. Not enough information to determine the causal relation

QUESTIONS 11

Rebecca has found 3 cases on “Deep Vein Thrombosis” from product search “Amlodipine Besylate.” Does she has enough information to determine that “Amlodipine Besylate” cause the reaction “Deep Vein Thrombosis?” Choose the best answer.

- a. “Amlodipine Besylate” caused serious “Deep Vein Thrombosis” reaction
- b. “Amlodipine Besylate” did not cause serious “Deep Vein Thrombosis” reaction
- c. “Amlodipine Besylate” may have caused “Deep Vein Thrombosis” reaction

d. Not enough information to determine the causal relation

One or more of these outcomes or reported reactions in a report does not necessarily mean that the suspect product of interest was the cause of the reported outcomes or reactions. Also reported narrative is not available in the public data.

LINE LISTING



Total number of cases based on applied filter

Sort Option

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction **Listing of Cases** Disclaimer Site Feedback Report a Problem FAQ

Amidopine Besylate

AMLODIPINE BESYLATE Total Cases 589 Serious Cases (including deaths) 567 Death Cases 59

Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Recel...
9371793	-	Amidopine Besylate	Intentional Overdose	Metabolic Acidosis; Hypotension; ST-Tachycardia; Overdose; A...	Serious	Hospitalized	Female	01-APR-2013	25-JUN-2013
8336357	Viagra	Sildenafil Citrate; Amidopine Besylate	Erectile Dysfunction; Hypertension	Drug Ineffective; Chest Pain; Wrong Technique In Product Usage	Serious	Other Outcomes	Male	01-JAN-2011	17-FEB-2012
10528890	Amidopine	Amidopine Besylate; Basiliximab; Tacrolimus	Hypertension; Immunosuppression; Used For Unknown Indication; Renal Transplant	Respiratory Rate Decreased; Bilirubin Conjugated	Serious	Hospitalized; Other Outcomes	Male	01-JUN-2014	20-OCT-2014
8482696	Bystolic; Norvasc	Nebivolol Hydrochloride; Amidopine Besylate	Cardiac Disorder; Heart Rate Irregular; Hypertension; Secure	Renal Failure; Palpitations; Abdominal Distension; Edema	Serious	Other Outcomes	Female	01-MAY-2011	06-APR-2012
8515582	Norvasc; Humira	Atalimumab; Amidopine Besylate; Lisinopril	Gastroesophageal Reflux Disease; Product Used For Unknown Indication; Psoriatic Arthritis	Headache; Edema; Peripheral; Palpitations; Potassium	Non-Serious	Non-Serious	Female	01-OCT-2011	18-MAY-2012
10217221	Vasotec; Lyrica; Entrel; Ampyra; Ryth...	Amidopine Besylate; Cyclobenzaprine Hydrochloride; Efenunomide; Piperacillin Sodium; Ticlopidine	Arthritis; Atrial Fibrillation; Hypertension; Blood Pressure Measurement; Fibromyalgia	Retching; Alopecia; Judgment Impaired; Mouth Ulceration; Fatigue; Colp...	Serious	Hospitalized; Other Outcomes	Female	02-FEB-2007	07-JUL-2014
11530606	Macrodantin; Cipro; Welbutrin; Macr...	Nitrofurantoin; Nitrofurantoin Monohydrate; Lisinopril; Bupropion Hydrochloride; Ciprofloxacin	Product Used For Unknown Indication	Loss Of Consciousness; Hypotension; Anorexia; Nutrient; Drug	Serious	Other Outcomes	Female	02-JUN-2015	16-OCT-2015
8256800	Amidopine; Herceptin	Trastuzumab; Amidopine Besylate; Epithelone D; Metoprolol Succinate; Carboplatin; Lorazepam	Breast Cancer; Product Used For Unknown Indication	Dehydration; Diarrhea	Serious	Hospitalized	Female	02-SEP-2005	31-MAY-2012
8646567	Lasix; And Hydrochlorothiazide; Amidopine; Co...	Carvedilol; Amidopine Besylate; Clonidine; Hydrochlorothiazide; Potassium; Investigational Product	Hypertension; Non-Small Cell Lung Cancer	Angiotensin; Hypotension; Atrial Fibrillation; Syncope; Acute Kidney Injury	Serious	Died; Other Outcomes; Disable...	Male	02-SEP-2012	02-SEP-2014
8647273	Coreg	Carvedilol; Clonidine; Hydrochlorothiazide; Potassium; Amidopine Besylate	Hypertension	Sepsis; Respiratory Distress Syndrome; Hypotension	Serious	Disabled; Other Outcomes; Died; H... Threatening	Male	02-SEP-2012	02-FEB-2013
10574105	Lioresal; Amidopine	Amidopine Besylate; Baclofen	Muscle Spasticity; Product Used For	Incorrect Route	Serious	Life	Male	03-OCT-2014	10-NOV-2014

Data as of August 31, 2017

Case IDs

Search within each displayed column

Additional columns available to view

LINE LISTING



FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ

AMLODIPINE BESYLATE Total Cases 589 Serious Cases (including deaths) 567 Death Cases 59

Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Recel...
9371793		Amiodipine Besylate	Intentional Overdose	Metabolic Acidosis,Hypotension,SI... Tachycardia,Overdose,A...	Serious	Hospitalized	Female	01-APR-2013	25-JUN-2013
8336357	Viagra	Sildenafil Citrate;Amiodipine Besylate	Erectile Dysfunction,Hypertension	Drug Ineffective,Chest Pain,Wrong Technique In Product Usage	Serious	Other Outcomes	Male	01-JAN-2011	17-FEB-2012
18528890	Amiodipine	Amiodipine Besylate,Basiliximab,Tacrolimus	Hypertension,Immunosuppression... Used For Unknown Indication,Renal Transplant	Respiratory Rate Decreased,Bilirubin Conjugated	Serious	Hospitalized;Other Outcomes	Male	01-JUN-2014	
8482696	Bystolic;Norvasc	Nebivolol Hydrochloride,Amiodipine Besylate	Cardiac Disorder,Heart Rate Irregular,Hypertension,Seizure	Renal Failure,Palpitations,Abd... Distension,Oedema	Serious	Other Outcomes	Female	01-MAY-2011	
8515582	Norvasc;Humira	Adalimumab,Amiodipine Besylate,Lisinopril	Gastroesophageal Reflux Disease;Product Used For Unknown Indication;Psoriatic Arthritis	Headache,Oedema Peripheral,Palpitations... Potassium	Non-Serious	Non-Serious	Female	01-OCT-2011	
10212221	Vasotec;Lyrica;Embrel;Amoyra;Ryth...	Amiodipine Besylate,Cyclobenzaprine Hydrochloride,Lefunomide,Piperacillin Sodium/Tazobactam	Arthritis,Atrial Fibrillation,Bl... Pressure Measurement,Fibromyalgia,Flu...	Retching,Alopecia,Judg... Impaired,Mouth Ulceration,Fatigue,Colp...	Serious	Hospitalized;Other Outcomes	Female	02-FEB-2007	
11538606	Macrochantin;Cipro;Wellbutrin;Macr...	Nitrofurantoin;Nitrofurantoin Monohydrate;Lisinopril;Bupropion Hydrochloride;Ciprofloxacin	Product Used For Unknown Indication	Loss Of Consciousness,Hypoten...	Serious	Other Outcomes	Female	02-JUN-2015	
8256800	Amiodipine;Herceptin	Trastuzumab,Amiodipine Besylate;Epothilone D;Metoprolol Succinate;Carboplatin;Lorazepam	Breast Cancer;Product Used For Unknown Indication	Dehydration,Dis...	Serious	Hospitalized	Female	02-SEP-2005	31-SEP-2012
8548567	Losartan;And Hydrochlorothiazide;Amiodipine;Co...	Carvedilol,Amiodipine Besylate;Clonidine;Hydrochlorothiazid... Potassium;Investigational Product	Hypertension;Non-Small Cell Lung Cancer	Anaesthesia,Hypertension,A... Respiratory Distress Syndrome	Serious	Died;Other Outcomes;Disabl...	Male	02-SEP-2012	02-SEP-2014
8847273	Coreg	Carvedilol,Clonidine;Hydrochlorothiazid... Potassium;Amiodipine Besylate	Hypertension	Sepsis,Acidotic Respiratory Distress Syndrome,Hy...	Serious	Disabled;Other Outcomes;Died;H... Threatening	Male	02-SEP-2012	15-FEB-2013
10574105	Lionelal;Amiodipine	Amiodipine Besylate;Saciifen	Muscle Spasticity/Product Used For	Incorrect Route...	Serious	Life	Male	03-OCT-2014	18-NOV-2014

Data as of August 31, 2017

Columns

- Outcomes
- Sex
- Event Date
- Latest FDA Received Date
- Case Priority
- Patient Age
- Patient Weight
- Sender

Total number of cases based on applied filter

Sort Option

Case IDs

Search within each displayed column

Additional columns available to view

LINE LISTING



Search within each displayed column

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases

AMLODIPINE BESYLATE

Total Cases 589 Serious Cases (including deaths) 567 Death Cases 59

Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Adverse Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Recel...
9371793	-	Amlodipine Besylate	Intentional Overdose	...	Serious	Hospitalized	Female	01-APR-2013	25-JUN-2013
8336357	Viagra	Sildenafil Citrate, Amlodipine Besylate	Erectile Dysfunction	...	Serious	Other Outcomes	Male	01-JAN-2011	17-FEB-2012
10528890	Amlodipine	Amlodipine Besylate, Basiliximab, Tacrolimus	Hypertension, Used For Living Transplant	...	Serious	Hospitalized, Other Outcomes	Male	01-JUN-2014	20-OCT-2014
8492696	Bystolic, Norvasc	Nebivolol Hydrochloride, Amlodipine Besylate	Cardiac Disorder, Irregular, Hypertension	...	Serious	Other Outcomes	Female	01-MAY-2011	06-APR-2012
8515582	Norvasc, Humira	Adalimumab, Amlodipine Besylate, Lisinopril	Gastroesophageal Disease, Product Indication, Poor	...	Non-Serious	Non-Serious	Female	01-OCT-2011	18-MAY-2012
10212221	Vasotec, Lyrica, Enbrel, Ampyra, Rytel	Amlodipine Besylate, Cyclobenzaprine Hydrochloride, Leflunomide, Piperacillin Sodium, Ticlopidine	Arthritis, Abnormal Pressure Measurement, Fibromyalgia, Fluid	...	Serious	Hospitalized, Other Outcomes	Female	02-FEB-2007	07-JUL-2014
11538666	Macrodantin, Cipro, Welbutrin, Macrobid	Nitrofurantoin, Nitrofurantoin Monohydrate, Lisinopril, Bupropion Hydrochloride, Claprofenoxacin	Product Used For Unknown Indication	...	Serious	Other Outcomes	Female	02-JUN-2015	10-OCT-2015
8258800	Amlodipine, Herceptin	Trastuzumab, Amlodipine Besylate, Epothilone D, Metoprolol Succinate, Carboplatin, Lorazepam	Breast Cancer, Product Used For Unknown Indication	...	Serious	Hospitalized	Female	02-SEP-2005	31-MAY-2012
8846567	Losartan And Hydrochlorothiazide, Amlodipine, Coreg	Carvedilol, Amlodipine Besylate, Clonidine, Hydrochlorothiazide, Potassium, Investigational Product	Hypertension, Non-Small Cell Lung Cancer	...	Serious	Died, Other Outcomes, Disability	Male	02-SEP-2012	04-SEP-2014
8847273	Coreg	Carvedilol, Clonidine, Hydrochlorothiazide, Potassium, Amlodipine Besylate	Hypertension	...	Serious	Disabled, Other Outcomes, Died, Threatening	Male	02-SEP-2012	15-FEB-2013
10574105	Lioresal, Amlodipine	Amlodipine Besylate, Baclofen	Muscle Spasticity, Product Used For	...	Serious	Life	Male	03-OCT-2014	10-NOV-2014

Data as of August 31, 2017



QUESTIONS 12

Rebecca got results of 589 total cases for “Amlodipine Besylate.” She finds the line listing is very useful and is curious to see all available data columns.

Is it possible to view all the columns at one time?

- a. Yes
- b. No

QUESTIONS 12

Rebecca got results of 589 cases for “Amlodipine Besylate” based on the filter applied. She finds the line listing is very useful and curious to see all available data columns. Is it possible to view all column at one time?

a. Yes

b. No

The export option is not yet available to view all data columns. The only way is to select from the column library to include in the screen to view.

QUESTIONS 13

Rebecca wants detailed narratives to perform further analysis on these reports. The narrative data column is not available to public. What is the best method to get to the full details of all ICSRs?

- a. Make a FOIA request with all 589 case
- b. Send a Request to DrugInfo@FDA.HHS.GOV
- c. Send a Request to FDA Helpdesk
- d. None of the above

CONCLUSION

- ❑ FAERS dashboard gives the public and industry a more user friendly platform for accessing FAERS reports
- ❑ FAERS dashboard makes adverse event data more accessible and transparent.
- ❑ Existence of a report does not establish causation
- ❑ Rates of occurrence cannot be established with reports

