

## **FDA warns about serious bleeding risk with over-the-counter antacid products containing aspirin**

### **Safety Announcement**

**[06-06-2016]** The U.S. Food and Drug Administration (FDA) is warning consumers about the risk of serious bleeding when using nonprescription, also known as over-the-counter or OTC, aspirin-containing antacid products to treat heartburn, sour stomach, acid indigestion, or upset stomach. Many other products for these conditions are available that do not contain aspirin.

These widely used products already contain [warnings](#) about this bleeding risk on their labels; however, we are continuing to receive reports of this serious safety issue. As a result, we will continue to evaluate this safety concern and plan to convene an advisory committee of external experts to provide input regarding whether additional FDA actions are needed.

OTC aspirin-antacid products are sold under various trade names, including Alka-Seltzer Original, Bromo Seltzer, Medique Medi Seltzer, Picot Plus Effervescent, Vida Mia Pain Relief, Winco Foods Effervescent Antacid and Pain Relief, and Zee-Seltzer Antacid and Pain Reliever. They are also available as generic products.

**Consumers** should always read the [Drug Facts label](#) carefully when purchasing or taking an OTC product to treat heartburn, acid indigestion, or sour or upset stomach. If the product contains aspirin, consider whether you should choose a product without aspirin to relieve your symptoms.

Aspirin is a commonly used pain reducer and fever reducer. It is a nonsteroidal anti-inflammatory drug (NSAID) that can increase the risk of bleeding, including in the stomach and gastrointestinal (GI) tract. Ask your pharmacist if you need help reading the Drug Facts label.

If you have one or more of the following risk factors, you may have a higher chance of serious bleeding when taking aspirin-containing antacid products:

- Are 60 years or older
- Have a history of stomach ulcers or bleeding problems
- Take a blood-thinning or steroid medicine
- Take other medicines containing NSAIDs such as ibuprofen or naproxen
- Drink three or more alcoholic drinks every day

Taking more of these medicines than the amount recommended or for a longer period than recommended will increase the risk of serious bleeding.

In 2009, a [warning](#) about the risk of serious bleeding was added to the labels of all OTC products that contain NSAIDs, including aspirin-containing antacid products. However, a search of the [FDA Adverse Event Reporting System \(FAERS\) database](#) identified eight cases of serious bleeding events associated with these products after the warning was added. All of these patients were hospitalized. Patients had underlying conditions such as the risk factors above that put them at greater risk for developing serious bleeding events (see Data Summary). The FAERS database includes only reports submitted to FDA so there are likely additional cases about which we are unaware.

We are continuing to evaluate this safety issue and will notify the public of the advisory committee meeting by posting notices in the [Federal Register](#) and on the [FDA Advisory Committees web page](#) and when we have additional information to share.

We urge consumers and health care professionals to report side effects involving OTC aspirin-containing antacid products or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

### **Facts about Over-the-counter (OTC) Aspirin-containing Antacid Products**

- These products combine an antacid (such as sodium bicarbonate or another antacid) that neutralizes stomach acid with aspirin, a nonsteroidal anti-inflammatory drug (NSAID).
- OTC aspirin-containing antacid products are widely used to treat heartburn, sour stomach, acid indigestion, or upset stomach, along with headache or body aches and pains.
- OTC aspirin-containing antacid products are sold under various trade names, including Alka-Seltzer Original, Bromo Seltzer, Medique Medi Seltzer, Picot Plus Effervescent, Vida Mia Pain Relief, Winco Foods Effervescent Antacid and Pain Relief, and Zee-Seltzer Antacid and Pain Reliever.

### **Additional Information for Consumers and Health Care Professionals**

- Serious bleeding events have been reported with the use of over-the-counter (OTC) medicines that contain a combination of an antacid to treat heartburn, sour stomach, acid indigestion, or upset stomach, and the pain reliever aspirin.
- When purchasing or taking an OTC product to treat heartburn, acid indigestion, upset stomach, or sour stomach, always read the [Drug Facts label](#) carefully. If the product contains aspirin, consider whether that product is right for you, or if you could choose a product without aspirin to relieve your symptoms. Many OTC products are available that relieve heartburn and stomach symptoms but do not contain aspirin.

- If you have one or more of the following risk factors, you may have a higher chance of serious bleeding when taking aspirin-containing antacid products:
  - Are 60 years or older
  - Have a history of stomach ulcers or bleeding problems
  - Take a medicine to reduce the ability of your blood to clot. These are also known as anticoagulants or blood-thinning drugs. Some examples include warfarin, dabigatran, rivaroxaban, apixaban, edoxaban, and heparin.
  - Take a steroid medicine to reduce inflammation. Some examples include prednisone, prednisolone, methylprednisolone, hydrocortisone, betamethasone, and dexamethasone.
  - Take other medicines containing nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or naproxen
  - Drink three or more alcoholic drinks every day
- Always read the [Drug Facts labels](#) included on antacids and all OTC medicines to find out if the product contains aspirin. Aspirin is an NSAID that can increase the risk of serious bleeding, including in the stomach, gastrointestinal (GI) tract, brain, and spinal cord.
- This serious bleeding can require hospitalization or the need for a blood transfusion.
- If you are not sure if a product contains aspirin, ask a pharmacist or your health care professional.
- Taking more of the medicine than the amount recommended or for a longer period than recommended will increase the risk of serious bleeding.
- If you are taking aspirin alone for your heart or for another reason, don't stop taking it without first talking to your health care professional.
- Report side effects from OTC aspirin-containing antacid products or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

## Data Summary

A search of the [FDA Adverse Event Reporting System \(FAERS\) database](#) from January 1, 1969 (database initiation), through August 13, 2014, identified 41 cases of serious bleeding events reported with over-the-counter (OTC) products containing aspirin, sodium bicarbonate, and citric acid. All patients experienced serious outcomes resulting in hospitalization, and 21 patients required transfusions due to the blood loss. Most of the patients recovered. One death was reported; however, the case provided few details of the patient's underlying medical conditions or the cause of death.

Of the 41 cases:

- 17 provided no details about the dosing
- 11 indicated the patient used the product routinely on a daily basis, ranging from once a day to six times a day or every 4 hours, which is within the recommended dosage
- Seven cases indicated the patient used the product as needed
- Three cases indicated the patient inappropriately used the product by taking more than the recommended maximum of eight tablets per day

- Three reported the patient used one dose of the product before developing the bleeding event
- For the 18 cases reporting a duration of use, the median time to onset of the bleeding event was 7.5 days (range of duration of use: a single day to 3 years)

The majority of patients using the aspirin-containing antacid products appeared to have had underlying conditions that put them at risk for developing serious bleeding events, particularly gastrointestinal bleeding events. Risk factors for developing bleeding were reported in 88% (36/41) of the cases, and included age greater than 60 years (n=23); use of anticoagulants, steroids, or nonsteroidal anti-inflammatory drugs (n=28); history of stomach ulcers (n=4); or history of alcohol abuse (n=5).

### **Related Information**

- [Bleeding Risk from Using OTC Antacids that Contain Aspirin](#)
- [Warning: Aspirin-Containing Antacid Medicines Can Cause Bleeding](#)
- [What's on the Label](#)
- [Think It Through: Managing the Benefits and Risks of Medicines](#)
- [Advisory Committees: Critical to the FDA's Product Review Process](#)