Drug Class Review Monograph – GPI Class 48 – Antacids

Review Time Frame: 02/2016 – 01/2017
Previous Class Review: N/A

Background:
Antacids neutralize gastric acid and usually contain one or more of the following: aluminum salts, bicarbonates, calcium salts, or magnesium salts.

New treatment guideline recommendations:
- None identified

Newly approved drugs:
- None identified

Newly approved formulations:
- None identified

Newly approved generics:
- None identified

Discontinued drugs:
- None identified

FDA Safety Alerts/black box warnings:
- 06/06/2016: FDA Drug Safety Communication: FDA warns about serious bleeding risk with over-the-counter antacid products containing aspirin (refer to page 2 for full detail).

Pipeline alerts:
Agents pending FDA approval include:
- None identified

References:

1. Vakil NB. Antiulcer medications: Mechanism of action, pharmacology, and side effects. Feldman M, Grover S. (Ed), UpToDate. Waltham MA. Accessed January 2017.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.
3. US Script Oracle PBM: Medi-Span® Master Drug Data Base. February 2017.
4. WWW.FDA.GOV.

(FDA Drug Safety Communication, continued from page 1)

FDA Drug Safety Communication: FDA warns about serious bleeding risk with over-the-counter antacid products containing aspirin
[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, the FDA is continuing to receive reports of this serious safety issue. As a result, the FDA 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. The FAERS database includes only reports submitted to FDA.