

Drug Class Review Monograph – GPI Class 49 – Ulcer Drugs

Review Time Frame: 11/2015 – 01/2017

Previous Class Review: 02/2016

Background:

Ulcer drugs reviewed in this class include:

- Antispasmodics – decrease the movements of the stomach and intestine as well as the secretions of stomach acid and digestive enzymes
- H2 antagonists – inhibit acid secretion by blocking histamine-2 receptors on the parietal cell
- Prostaglandins (e.g., misoprostol) – inhibit basal and nocturnal gastric acid secretion through direct action on the parietal cell
- Proton pump inhibitors – block the secretion of gastric acid by the gastric parietal cells
- Miscellaneous anti-ulcer agent (e.g., sucralfate) – forms a protective coating that acts locally to protect the gastric lining
- Ulcer therapy combinations

New treatment guideline recommendations:

- None identified

Newly approved drugs:

- None identified

Newly approved formulations:

- Approved 06/07/2016: Lansoprazole 15 mg delayed-release orally disintegrating tablets; over-the-counter (OTC) product not commercially available.
- Approved 01/26/2016: Dexilant (dexlansoprazole) 30 mg delayed-release orally disintegrating tablets; currently not commercially available-anticipated launch date is unknown.
- Approved 11/23/2015: Nexium (esomeprazole) 24 HR 20 mg delayed-release tablets; commercially available OTC.

Newly approved generics:

- None identified

Discontinued drugs:

- None identified

FDA Safety Alerts/black box warnings:

- None identified

Pipeline alerts:

Agents pending FDA approval include:

- None identified

Commented [NVB1]: So I'm not sure this is really needed. I was originally gonna suggest adding a description similar to the descriptions above it (something to the effect of "manage ulcers with multiple mechanisms by combining the various agents above") but it doesn't add that much... I wonder if you should just delete it? Or maybe you could be like:

Ulcer drugs reviewed in this class include:

- Class1
- Class2
- Class3 etc

Some of these agents can be found in combination products.

If you decide to leave it, I think that's ok too. Just a suggestion!

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. Weinhouse GL. Stress ulcer prophylaxis in the intensive care unit. Manaker S, Finlay G. (Ed), UpToDate. Waltham MA. Accessed January 2016.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed February 2017.
4. US Script Oracle PBM: Medi-Span® Master Drug Data Base. February 2017.
5. WWW.FDA.GOV.