Proton pump inhibitors – New warning

- On June 7, 2018, the FDA approved an update to the Warnings and Precautions section of the proton pump inhibitors’ (PPIs) drug labels regarding fundic gland polyps.

- The following brand and generic PPIs or combination products with PPIs affected include Dexilant® (dexlansoprazole), Vimovo® (naproxen/esomeprazole), Yosprala® (aspirin/omeprazole), esomeprazole (Nexium®), esomeprazole strontium, lansoprazole (Prevacid®), omeprazole (Prilosec®), omeprazole/sodium bicarbonate (Zegerid®), pantoprazole (Protonix®), and rabeprazole (AcipHex®, AcipHex Sprinkle®)

  — PPIs are used to treat a variety of gastrointestinal disorders such as gastroesophageal reflux disease, nonsteroidal anti-inflammatory drug-induced gastric ulcers, Helicobacter pylori eradication to prevent duodenal ulcer recurrence, and Zollinger-Ellison syndrome.

  — Consult individual drug labels for specific indication recommendations.

- PPI use is associated with an increased risk of fundic gland polyps that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy.

  — Use the shortest duration of PPI therapy appropriate to the condition being treated.