

## 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 <a href="Dexilant@">Dexilant@</a>
  (dexlansoprazole), Vimovo® (naproxen/esomeprazole), Yosprala® (aspirin/omeprazole), esomeprazole (<a href="Nexium">Nexium</a>
  (naproxen/esomeprazole), Yosprala® (aspirin/omeprazole), esomeprazole (<a href="Nexium">Nexium</a>
  (naproxen/esomeprazole), Yosprala® (aspirin/omeprazole), esomeprazole (<a href="Prevacide">Nexium</a>
  (naproxen/esomeprazole), Yosprala® (aspirin/omeprazole), omeprazole (<a href="Prevacide">Prevacide</a>
  (naproxen/esomeprazole), Yosprala® (aspirin/omeprazole), omeprazole (<a href="Prevacide">Prevacide</a>
  (naproxen/esomeprazole), Yosprala® (aspirin/omeprazole), esomeprazole (<a href="Prevacide">Prevacide</a>
  (naproxen/esomeprazole), Yosprala® (aspirin/omeprazole), esomeprazole (<a href="Prevacide">Prevacide</a>
  (naproxen/esomeprazole), pantoprazole (<a href="Pre
  - 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.



## optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum<sup>®</sup> trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.