

Prevacid[®], Prevacid[®] SoluTab[™] (lansoprazole) – New warnings

- On October 19, 2017, the <u>FDA approved</u> updates to the *Warning and Precautions* section of the <u>Prevacid (lansoprazole)</u> and <u>Prevacid SoluTab (lansoprazole)</u> drug labels, regarding interactions with investigations for neuroendocrine tumors and risks in patients with phenylketonuria (PKU).
- Prevacid and Prevacid SoluTab are indicated for the following:
 - Treatment of active duodenal ulcer
 - Eradication of H. pylori to reduce the risk of duodenal ulcer recurrence
 - Maintenance of healed duodenal ulcers
 - Treatment of active benign gastric ulcer
 - Healing of nonsteroidal anti-inflammatory drug (NSAID)-associated gastric ulcer
 - Risk reduction of NSAID-associated gastric ulcer
 - Treatment of symptomatic gastroesophageal reflux disease
 - Treatment of erosive esophagitis (EE)
 - Maintenance of healing of EE
 - Pathological hypersecretory conditions including Zollinger-Ellison Syndrome
- Information regarding interactions with investigations for neuroendocrine tumors was added to the *Warnings and Precautions* section.
 - Serum chromogranin A (CgA) levels increase secondary to drug-induced decreases in gastric acidity. The increased CgA level may cause false positive results in diagnostic investigations for neuroendocrine tumors.
 - Healthcare providers should temporarily stop lansoprazole treatment at least 14 days before
 assessing CgA levels and consider repeating the test if initial CgA levels are high. If serial
 tests are performed (eg, for monitoring), the same commercial laboratory should be used for
 testing, as reference ranges between tests may vary.
- Information regarding patients with PKU was also added to the Warnings and Precautions section.
 - Phenylalanine can be harmful to patients with PKU. Prevacid SoluTab contains phenylalanine, a component of aspartame. Each 15 mg tablet contains 2.5 mg and each 30 mg tablet contains 5.1 mg of phenylalanine.
 - Before prescribing Prevacid SoluTab to a patient with PKU, consider the combined daily amount of phenylalanine from all sources, including Prevacid SoluTab.
- Consistent with the drug label for <u>rilpivirine</u>, proton pump inhibitors, including Prevacid and Prevacid SoluTab, are contraindicated with rilpivirine-containing products.



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[®] 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.

©2017 Optum, Inc. All rights reserved.