

DEXILANT (DEXLANSOPRAZOLE) PRODUCT LABELING UPDATED TO STATE NO DOSE ADJUSTMENT OF CLOPIDOGREL (PLAVIX) NECESSARY WHEN ADMINISTERED WITH APPROVED DOSE OF DEXILANT

The DEXILANT (dexlansoprazole) prescribing labeling now includes information from a study in healthy subjects demonstrating that DEXILANT had no clinically important effect on exposure to the active metabolite of clopidogrel (Plavix) or clopidogrel-induced platelet inhibition. No dose adjustment of clopidogrel is necessary when administered with an approved dose of DEXILANT. DEXILANT is a proton pump inhibitor (PPI) indicated for the treatment of gastroesophageal reflux disease (GERD). GERD affects nearly 19 million Americans.

Clopidogrel is an antiplatelet drug that is indicated for the reduction of atherothrombotic events in patients with acute coronary syndromes, recent myocardial infarction, recent stroke or established peripheral arterial disease. Takeda conducted a randomized, open-label, two-period, crossover study, to evaluate the effect of DEXILANT on the pharmacokinetics and pharmacodynamics of clopidogrel in healthy subjects. The study showed that the area under the curve of the active metabolite of clopidogrel was reduced by approximately 9 percent (mean AUC ratio was 91 percent, with 90 percent CI of 86-97 percent) when DEXILANT was coadministered compared to administration of clopidogrel alone.

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About GERD

FOUR FACTS ABOUT GERD

- When stomach acid used for digestion repeatedly backs up, or refluxes, into the esophagus it can cause heartburn.
- GERD affects different people in many different ways. Persistent heartburn is the most common symptom.
- The symptoms of GERD, like heartburn, can be reduced by avoiding foods and beverages that may trigger them, such as citrus and spicy foods.
- Occasional heartburn is often treatable with over-the-counter medication and/or lifestyle modification, but heartburn that occurs two or more days a week despite treatment and diet changes could be GERD. People with GERD should consult their doctor.

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About DEXILANT

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[How DEXILANT Works](#)

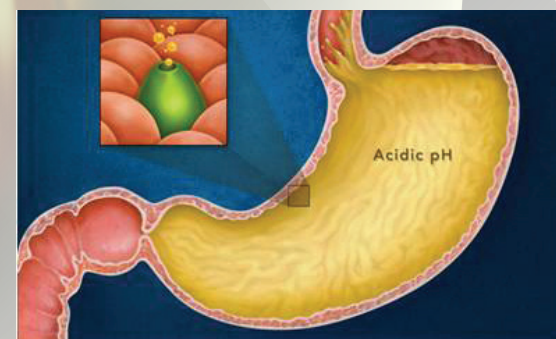
[DEXILANT Prescribing Labeling Update](#)



David Johnson, M.D.,
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See

SEE HOW DEXILANT WORKS



About DEXILANT (dexlansoprazole) 30 mg and 60 mg delayed release capsules

DEXILANT is a PPI, which decreases acid production by turning off many of the acid pumps in the stomach, thus helping to protect the esophagus from acidic reflux so that esophageal inflammation can heal. DEXILANT combines an enantiomer of lansoprazole with a Dual Delayed Release (DDR) formulation designed to provide two separate releases of medication. DEXILANT is indicated for healing all grades of erosive esophagitis (EE) for up to 8 weeks, maintaining healing of EE and relief of heartburn for up to 6 months, and treating heartburn associated with symptomatic non-erosive GERD for 4 weeks.

Important Safety Information

DEXILANT is contraindicated in patients with known hypersensitivity to any component of the formulation. Hypersensitivity and anaphylaxis have been reported with DEXILANT use. Symptomatic response with DEXILANT does not preclude the presence of gastric malignancy. Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Hypomagnesemia has been reported rarely with prolonged treatment with PPIs.

Most commonly reported adverse reactions were diarrhea (4.8%), abdominal pain (4.0%), nausea (2.9%), upper respiratory tract infection (1.9%), vomiting (1.6%), and flatulence (1.6%). Do not co-administer atazanavir with DEXILANT because atazanavir systemic concentrations may be substantially decreased. DEXILANT may interfere with absorption of drugs for which gastric pH is important for bioavailability (e.g., ampicillin esters, digoxin, iron salts, ketoconazole). Patients taking concomitant warfarin may require monitoring for increases in international normalized ratio (INR) and prothrombin time. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Concomitant tacrolimus use may increase tacrolimus whole blood concentrations.

Please see accompanying [full prescribing information](#) and visit the DEXILANT Website at www.DEXILANT.com.

DEXILANT™
dexlansoprazole
30 MG | 60 MG DELAYED RELEASE CAPSULES
Two releases. One pill.

