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Dexilant

(Dexlansoprazole) - Takeda

THERAPEUTIC CLASS

Proton pump inhibitor

DEA CLASS

RX

INDICATIONS

Healing of all grades of erosive esophagitis (EE) for up to 8 weeks. Maintenance of healed EE and relief of heartburn for up to 6 months. Treatment of heartburn associated with symptomatic nonerosive gastroesophageal reflux disease (GERD) for 4 weeks.

ADULT DOSAGE

Adults: Healing of EE: 60mg qd for up to 8 weeks. Maint of Healed EE/Relief of Heartburn: 30mg qd for up to 6 months. Symptomatic Nonerosive GERD: 30mg qd for 4 weeks. Moderate Hepatic Impairment (Child-Pugh Class B): Max: 30mg qd.

HOW SUPPLIED

Cap, Delayed-Release: 30mg, 60mg

WARNINGS/PRECAUTIONS

Symptomatic response does not preclude the presence of gastric malignancy. May increase risk of *Clostridium difficile*-associated diarrhea (CDAD), especially in hospitalized patients. May increase risk for osteoporosis-related fractures of the hip, wrist, or spine, especially with high-dose and long-term therapy. Use lowest dose and shortest duration appropriate to the conditions being treated. Hypomagnesemia reported and may require Mg²⁺ replacement and discontinuation of therapy; consider monitoring Mg²⁺ levels prior to and periodically during therapy with prolonged treatment.

ADVERSE REACTIONS

Diarrhea, abdominal pain, N/V, upper respiratory tract infection, flatulence.

DRUG INTERACTIONS

May substantially decrease atazanavir concentrations; avoid concurrent use. May interfere with the absorption of drugs where gastric pH is an important determinant of oral bioavailability (eg, ampicillin esters, digoxin, iron salts, ketoconazole, erlotinib). Monitor for increases in INR and PT with warfarin. May increase tacrolimus levels. Caution with digoxin or other drugs that may cause hypomagnesemia (eg, diuretics). May elevate and prolong levels of methotrexate (MTX) and/or its metabolite, possibly leading to toxicities; consider temporary withdrawal of therapy with high-dose MTX.

PREGNANCY

Category B, not for use in nursing.

MECHANISM OF ACTION

Proton pump inhibitor; suppresses gastric acid secretion by specific inhibition of the (H⁺/K⁺)-ATPase in the gastric parietal cell. Blocks the final step of acid production.

PHARMACOKINETICS

Absorption: C_{max}=658ng/mL (30mg), 1397ng/mL (60mg); AUC₂₄=3275ng•hr/mL (30mg), 6529ng•hr/mL (60mg); T_{max}=1-2 hrs (1st peak), 4-5 hrs (2nd peak). **Distribution:** V_d=40.3L; plasma protein binding (96.1-98.8%). **Metabolism:** Liver (extensive) via CYP3A4 (oxidation) and CYP2C19 (hydroxylation). **Elimination:** Urine (50.7%), feces (47.6%); T_{1/2}=1-2 hrs.

ASSESSMENT

Assess for hypersensitivity to the drug, risk for osteoporosis-related fractures, hepatic impairment, pregnancy/nursing status, and possible drug interactions. Obtain baseline Mg²⁺ levels.

MONITORING

Monitor for signs/symptoms of CDAD, bone fractures, hypersensitivity reactions, and other adverse reactions. Monitor Mg²⁺ levels periodically. Monitor INR and PT when given with warfarin.

PATIENT COUNSELING

Instruct to watch for signs of an allergic reaction, as these could be serious and may require discontinuation. Advise to immediately report and seek care for diarrhea that does not improve, and for any cardiovascular/neurological symptoms (eg, palpitations, dizziness, seizures, tetany). Instruct to take up and to inform physician of any other medication use.

ADMINISTRATION/STORAGE

Administration: Oral route. Take without regard to food. Swallow cap whole; do not chew. Refer to PI for alternate administration options.

Storage: 25°C (77°F); excursions permitted to 15-30°C (59-86°F).