Dexilant (dexlansoprazole) - Drug Summary

Takeda Pharmaceuticals America, Inc.

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Dexilant
(dexlansoprazole)

THERAPEUTIC CLASS

Proton pump inhibitor (PPI)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Erosive Esophagitis

Healing:
60mg qd for up to 8 weeks

Maint of Healed Erosive Esophagitis and Relief of Heartburn:
30mg qd for up to 6 months

Symptomatic Nonerosive Gastroesophageal Reflux Disease

30mg qd for 4 weeks

DOSING CONSIDERATIONS

Hepatic Impairment
Moderate (Child-Pugh Class B):
Max Dose: 30mg qd

ADMINISTRATION

Oral route

Take w/o regard to food
Swallow cap whole; do not chew

Administration w/ Applesauce
Open cap and sprinkle intact granules on 1 tbsp of applesauce
Swallow immediately; do not chew granules

Administration w/ Water in an Oral Syringe
Open the cap and empty the granules into 20mL of water
Withdraw the entire mixture into a syringe and gently swirl the syringe
Administer immediately
Refill the syringe 2 more times w/ 10mL of water, swirl gently, and administer

Administration w/ Water Via a Nasogastric Tube (≥16 French)
Open the cap and empty the granules into 20mL of water
Withdraw the entire mixture into a catheter-tip syringe
Swirl the syringe gently and immediately inject the mixture through the NG tube into the stomach
Refill the syringe w/ 10mL of water, swirl gently, and flush the tube
Refill the syringe again w/ 10mL of water, swirl gently, and administer

HOW SUPPLIED

Cap, Delayed-Release: 30mg, 60mg

WARNINGS/PRECAUTIONS

Symptomatic response does not preclude the presence of gastric malignancy. Acute interstitial nephritis reported; d/c if this develops. Cyanocobalamin (vitamin B12) deficiency may occur due to malabsorption with daily long-term treatment (eg, >3 yrs) with any acid-suppressing medications. 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 Mg^{2+} replacement and discontinuation of therapy; consider monitoring Mg^{2+} levels prior to and periodically during therapy with prolonged treatment.

ADVERSE REACTIONS

Diarrhea, abdominal pain, nausea, URTI.

DRUG INTERACTIONS

May reduce absorption of drugs where gastric pH is an important determinant of their bioavailability; ampicillin esters, ketoconazole, atazanavir, iron salts, erlotinib, and mycophenolate mofetil (MMF) absorption can decrease, while digoxin absorption can increase. May substantially decrease atazanavir concentrations; avoid concurrent use. Caution in transplant patients receiving MMF. 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 MTX and/or its metabolite, possibly leading to toxicities; consider temporary withdrawal of therapy with high-dose MTX.

PREGNANCY AND LACTATION

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); AUC_{24}=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 Mg^{2+} levels.

MONITORING

Monitor for signs/symptoms of acute interstitial nephritis, cyanocobalamin deficiency, CDAD, bone fractures, hypersensitivity reactions, and other adverse reactions. Monitor Mg^{2+} 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 ud and to inform physician of any other medication use.

STORAGE

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

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