Dexogut

Dexlansoprazole

Presentation

Dexogut 30 mg Capsule: Each capsule contains 30 mg Dexlansoprazole INN as dual delayed release enteric coated pellets.
Dexogut 60 mg Capsule: Each capsule contains 60 mg Dexlansoprazole INN as dual delayed release enteric coated pellets.

Description

The active ingredient dexlansoprazole delayed- release capsules, a proton pump inhibitor inhibits gastric acid secretion. Dexlansoprazole is the R-enantiomer of lansoprazole.Dexlansoprazole is stable when exposed to light. Dexlansoprazole is more stable in neutral and alkaline conditions than acidic conditions.Dexlansoprazole is supplied as a dual delayed-release formulation in capsules for oral administration. The capsules contain dexlansoprazole in a mixture of two types of enteric-coated granules with different pH-dependent dissolution profiles.

Mechanism of Action

Dexlansoprazole is a PPI that suppresses gastric acid secretion by specific inhibition of the (H+,K+)-ATPase in the gastric parietal cell. By acting specifically on the proton pump, dexlansoprazole blocks the final step of acid production.

Indications

- Healing of Erosive Esophagitis
- Maintenance of Healed Erosive Esophagitis
- Symptomatic Non-Erosive Gastroesophageal Reflux Disease

Dosage and Administration

Recommended Dose

Dexlansoprazoleis available as capsules in 30 mg and 60 mg strengths for adult use. Directions for use in each indication are summarized in Table.

Table: Dexlansoprazole Dosing Recommendations

Indication	Recommended Dose	Frequency
Healing of EE	60 mg	Once daily for up to 8 weeks
Maintenance of Healed EE and relief of heartburn	30 mg	Once daily up to 6 months
Symptomatic Non-Erosive GERD	30 mg	Once daily for 4 weeks

Side Effects

Adverse events are rarely seen; such as diarrhea, abdominal pain, nausea, vomiting, flatulence ect.

Drug Interactions

Dexlansoprazoleis likely to substantially decrease the systemic concentrations of the HIV protease inhibitor atazanavir, which is dependent upon the presence of gastric acid for absorption, and may result in a loss of therapeutic effect of atazanavir and the development of HIV resistance. Therefore, Dexlansoprazoleshould not be co-administered with atazanavir. Dexlansoprazolemay interfere with the absorption of other drugs where gastric pH is an important determinant of oral bioavailability (e.g., ampicillin esters, digoxin, iron salts, ketoconazole).

Warfarin

Co-administration of Dexlansoprazole90 mg and warfarin 25 mg did not affect the pharmacokinetics of warfarin or INR. However, there have been reports of increased INR and prothrombin time in patients receiving PPIs and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with Dexlansoprazoleand warfarin concomitantly may need to be monitored for increases in INR and prothrombin time.

Tacrolimus

Concomitant administration of dexlansoprazole and tacrolimus may increase whole blood levels of tacrolimus, especially in transplant patients who are intermediate or poor metabolizers of CYP2C19.

Methotrexate

Case reports, published population pharmacokinetic studies, and retrospective analyses suggest that concomitant administration of PPIs and methotrexate (primarily at high dose; see methotrexate prescribing information) may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate. However, no formal drug interaction studies of high-dose methotrexate with PPIs have been conducted.

Contraindications

Dexlansoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

Use in Specific Populations

Pregnancy

Pregnancy Category B. There are no adequate and well-controlled studies with dexlansoprazole in pregnant women. There were no adverse fetal effects in animal reproduction studies of dexlansoprazole in rabbits. Because animal reproduction studies are not always predictive of human response, dexlansoprazole should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether dexlansoprazole is excreted in human milk. However, lansoprazole and its metabolites are present in rat milk following the administration of lansoprazole. As many drugs are excreted in human milk, and because of the potential for tumorigenicity shown for lansoprazole in rat carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of dexlansoprazole in pediatric patients (less than 12 years of age) have not been established.

Geriatric Use

In clinical studies of dexlansoprazole, 11% of patients were aged 65 years and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified significant differences in responses between geriatric and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

No dosage adjustment of dexlansoprazole is necessary in patients with renal impairment. The pharmacokinetics of dexlansoprazole in patients with renal impairment are not expected to be altered since dexlansoprazole is extensively metabolized in the liver to inactive metabolites, and no parent drug is recovered in the urine following an oral dose of dexlansoprazole.

Hepatic Impairment

No dosage adjustment for dexlansoprazole is necessary for patients with mild hepatic impairment (Child-Pugh Class A). dexlansoprazole 30 mg should be considered for patients with moderate hepatic impairment (Child-Pugh Class B). No studies have been conducted in patients with severe hepatic impairment (Child-Pugh Class C).

Warnings and Precautions

Gastric Malignancy: Symptomatic response with dexlansoprazoledoes not preclude the presence of gastric malignancy.

Clostridium Difficile Associated Diarrhea: Published observational studies suggest that PPI therapy like dexlansoprazolemay be associated with an increased risk of Clostridium difficile associated diarrhea, especially in hospitalized patients. This diagnosis should be considered for diarrhea that does not improve.
Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.

Bone Fracture: Several published observational studies suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the conditions being treated. Patients at risk for osteoporosis-related fractures should be managed according to established treatment guidelines.

Hypomagnesemia: Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. In most patients, treatment of hypomagnesemia required magnesium replacement and discontinuation of the PPI.
For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics), health care professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically.

Concomitant use of dexlansoprazolewith Methotrexate: Literature suggests that concomitant use of PPIs with methotrexate (primarily at high dose; see methotrexate prescribing information) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. In high-dose methotrexate administration, a temporary withdrawal of the PPI may be considered in some patients.

Overdosage

There have been no reports of significant overdose of Dexlansoprazole. It is not expected to be removed from the circulation by hemodialysis. If an overdose occurs, treatment should be symptomatic and supportive.

Pharmaceutical Precautions

Store in a cool dry place. Keep away from light and moisture. Keep out of reach of children.

Commercial Packs

Dexogut 30 mg Capsule: Each commercial box contains 5X10 capsules in Alu-Alu blister pack.
Dexogut 60 mg Capsule: Each commercial box contains 3X10 capsules in Alu-Alu blister pack.

Manufactured by :

POPULAR

POPULAR PHARMACEUTICALS LTD.

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