Delanix®

Dexlansoprazole Capsule

1395

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Presentation

Delanix® 30 capsule: Each capsule contains Dexlansoprazole INN 30 mg as enteric coated pellets.
Delanix® 60 capsule: Each capsule contains Dexlansoprazole INN 60 mg as enteric coated pellets.

Description

Delanix® (Dexlansoprazole) delayed release capsule has been characterized as a gastric Proton Pump Inhibitor (PPI) that blocks the final step of gastric acid production. It is the R-enantiomer of Lansoprazole (a racemic mixture of the R- and S-enantiomers). Dexlansoprazole capsule contains a mixture of two type of enteric coated pellets with different pH-dependent dissolution profiles.

The formulation of Delanix® (Dexlansoprazole) utilizes Dual Delayed Release (DDR) technology which results in plasma concentration-time profile with two distinct peak; the first peak occurs within 1 to 2 hours after administration, followed by a second peak within 4 to 5 hours. No accumulation of Dexlansoprazole occurs after multiple once daily doses of Delanix® 30 mg or 60 mg.

Indications and Uses

Delanix® (Dexlansoprazole) is a Proton Pump Inhibitor (PPI) used to treat-

1. Healing of all grades of Erosive Esophagitis
2. Maintenance of healed Erosive Esophagitis
3. Heartburn associated with Non-Erosive Gastroesophageal reflux disease (GERD)

Dosage and Administration

Delanix® (Dexlansoprazole) capsule is administered orally. The recommended dose of Dexlansoprazole for adults are as follows:

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

Side Effect

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

Precaution

Patients taking concomitant Warfarin may require monitoring for increased International Normalized Ratio (INR) and Prothrombin Time. Increased INR and Prothrombin Time may lead to abnormal bleeding and even death.

Use in Pregnancy and Lactation

Dexlansoprazole is considered a US FDA Pregnancy Category B drug. This means that Dexlansoprazole is probably safe for use during pregnancy, although the full risks are currently unknown.

Contraindication

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

Drug Interactions

Dexlansoprazole may interfere with the absorption of drugs for which gastric pH is important for bioavailability (e.g., Ampicillin esters, Digoxin, Iron salts, Ketoconazole). Concomitant administration of dexlansoprazole and clopidogrel in healthy subjects had no clinically important effect on exposure to the active metabolite of clopidogrel or clopidogrel-induced platelet inhibition. No dose adjustment of clopidogrel is necessary when administered with an approved dose of Delanix®.

Overdose

There have been no reports of significant overdose of Dexlansoprazole. Multiple doses of Dexlansoprazole 120 mg and a single dose of Dexlansoprazole 300 mg did not result in any severe adverse events.

Storage

Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial Pack

Delanix® 30 capsule: Each box contains 5 alu-alu blister strips of 10 capsules.
Delanix® 60 capsule: Each box contains 3 alu-alu blister strips of 10 capsules.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

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