Ranola

Ranolazine 500 mg ER Tablet

Presentation

Ranola : Each extended release film coated tablet contains Ranolazine INN 500 mg.

Pharmacodynamic Properties

Ranolazine is a specific inhibitor of late sodium current at therapeutic levels. During ischemic episodes excess sodium can flow into cardiac cells through sodium channels. This excess sodium can trigger a subsequent overload of calcium that can lead to problems with proper contraction and relaxation of the heart. Late sodium current inhibition has been shown to improve mechanical and electrical dysfunctions of cardiac cells under these circumstances.

Pharmacokinetic Properties

Absorption : C max : 2 - 5 h
Half life : 6 - 22 h
Distribution : Over the concentration range of 0.25 to 10 µg/ml, Ranolazine is approximately 62% bound to human plasma proteins.
Metabolism and Excretion : Ranolazine is metabolized mainly by CYP3A and, to a lesser extent, by CYP2D6. Ranolazine is metabolized rapidly and extensively in the liver and intestine; less than 5% is excreted unchanged in urine and feces. Following a single oral dose of Ranolazine solution, approximately 75% of the dose is excreted in urine and 25% in feces.

Indications

Ranolazine is indicated for the treatment of chronic angina.

Dosage and Administration

The initial dose of Ranolazine is 500 mg twice daily and can be increased up to 1000 mg twice daily, as needed, and based on clinical symptoms. Ranolazine can be taken with or without meals.
The maximum recommended daily dose of Ranolazine is 1000 mg twice daily.

Contraindications

It is contraindicated in patients:

* Taking strong inhibitors of CYP3A
* With clinically significant hepatic impairment

Precautions

Co-administration of Ranolazine and Digoxin increases the plasma concentrations of Digoxin by approximately 1.5-fold and the dose of Digoxin may have to be reduced accordingly. The dose of other P-gp substrates may have to be reduced as well as Ranolazine is co-administered.
Ranolazine can inhibit the activity of CYP2D6 and thus the metabolism of drugs that are mainly metabolized by this enzyme, the dose of such drugs may have to be reduced when Ranolazine is co-administered.

Drug Interactions

* CYP3A4 inhibitors
* QT interval prolonging drugs
* P-gp inhibitors
* P-gp substrates
* CYP450 2D6 substrates
* Paroxetine
* Simvastatin

Use in Pregnancy and Lactation

Use in Pregnancy : Pregnancy Category C
Lactation : Undetermined

Side Effects

* Dizziness, headache, constipation, nausea, asthenia
* Syncope, palpitations
* Vertigo
* Abdominal pain, vomiting, dry mouth
* Peripheral edema, dyspnea
* Bradycardia, hypotension, tremor, blurry vision, hypoesthesia, hematuria
* Transient eosinophilia, decreased hematocrit

Overdose

High oral doses of Ranolazine produce dose-related increases in dizziness, nausea, and vomiting. High intravenous exposure also produces diplopia, paresthesia, confusion, and syncope. In addition to general supportive measures, continuous ECG monitoring may be warranted in the event of overdose. Since Ranolazine is about 62% bound to plasma proteins, hemodialysis is unlikely to be effective in clearing Ranolazine.

Storage Conditions

Store in a cool & dry place, away from light and out of children's reach.

Commercial Pack

Ranola : Each box contains 2 blister packs of 10 tablets.

Manufactured by:
general GENERAL Pharmaceuticals Ltd.
Gazipur, Bangladesh
GENERAL Pharmaceuticals Ltd. ISO 9001:2008 Certified Company
UKAS