گولیاں

ٹروپیزول®

پینٹوپرازول سوڈیم

علامات:

ٹروپیزول خوراک کی نالی معدے اور بڑی آنت کی سوزش اور زخم سے آرام کے لیے موثر دوا ہے۔

خوراک:

ٹروپیزول کی عمومی ابتدائی خوراک ۴۰ ملی گرام روزانہ ہے جو کہ آرام نہ آنے کی صورت میں ۸۰ ملی گرام روزانہ تک بڑھائی جا سکتی ہے۔ معدے کے السر میں ٹروپیزول کو اینٹی بیکٹیریل ادویات کے ساتھ تجویز کیا جا سکتا ہے۔ علاج کا دورانیہ ۴ سے ۱۲ ہفتوں تک ہے۔ جو آرام نہ آنے کی صورت میں مزید ۱۲ ہفتوں تک بڑھایا جا سکتا ہے۔

ہدایات:

* دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
* یہ دوا صرف ڈاکٹری ہدایات کے مطابق استعمال کریں۔
* دوا کو توڑے یا چبائے بغیر پانی سے نگل لیں۔

پیکنگ:

ٹروپیزول انٹیرک کوٹڈ گولیاں (۱×۲۰) ایلومینیم بلسٹر پیک میں دستیاب ہیں۔

Manufactured
Schazoo Zaka (Pvt) Ltd.
Lalliwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Tropizol®

Tablets

Pantoprazole Sodium

Gastro-resistant

COMPOSITION:
Each Enteric coated tablet contains:
Pantoprazole (as sodium sesquihydrate) Sch. Specs. .....40 mg

CLINICAL PHARMACOLOGY:
Mechanism of Action:
Pantoprazole is a proton pump inhibitor that suppresses the final step in gastric acid production by covalently binding to the (H-,K-)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding to the (H-,K-)-ATPase results in a duration of antisecretory effect that persists longer than 24 hours for all doses.

Pharmacokinetics:
Absorption: The absorption of pantoprazole is rapid, with C_{max} of 2.5µg/ml that occurs approximately 2.5 hours after single or multiple oral 40 mg doses. Pantoprazole is well absorbed; it undergoes little first pass metabolism resulting in an absolute bioavailability of approximately 77%. Pantoprazole absorption is not affected by concomitant administration of antacids.
Administation of pantoprazole with food may delay its absorption up to 2 hours or longer; however, the C_{max} and the extent of pantoprazole absorption (AUC) are not altered. Thus, pantoprazole may be taken without regard to timing of meals.

Distribution: The apparent volume of distribution of pantoprazole is approximately 11.0-23.6L, distributing mainly in extracellular fluid. The serum protein binding of pantoprazole is about 98%, primarily to albumin.

Metabolism: Pantoprazole is extensively metabolized in the liver through the cytochrome P450 system. Pantoprazole metabolism is independent of the route of administration. The main metabolic pathway is demethylation, by CYP2C19, with subsequent sulfation; other metabolic pathways include oxidation by CYP3A4.

Excretion: After a single oral dose of pantoprazole, approximately 71% of the dose is excreted in the urine with 18% excreted in the feces through biliary excretion. There is no renal excretion of unchanged pantoprazole.

INDICATIONS:
Tropizol is indicated for,
- The short term treatment in the healing and symptomatic relief of erosive esophagitis. Maintenance of healing of erosive esophagitis

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and reduction in relapse rates of day and night time heartburn symptoms in patients with gastroesophageal reflux disease.
- The eradication of Helicobacter Pylori in Peptic ulceration.
- Duodenal ulceration, and
- Gastric ulceration.

DOSAGE & ADMINISTRATION:
The usual dose for the treatment of duodenal ulcer, gastric ulcer and reflux oesophagitis is 40 mg once daily. In individual cases the dose may be doubled, 80 mg daily particularly when there has been no response to other medications. In patients with severe liver impairment the dose may be reduced to 1 tablet (40 mg).
Combination therapy:
In case of duodenal or gastric ulcer in which infection with Helicobacter pylori has been confirmed, the microorganism should be eradicated by combination treatment. Depending on resistance pattern, the following combinations are recommended:
Tropizol 40mg twice daily combined with,
- Amoxicillin 1000mg + Metronidazole 500mg both twice daily,
- Clarithromycin 500mg + Metronidazole 500mg both twice daily,
- Amoxicillin 1000mg + Clarithromycin 500mg both twice daily,
Combination therapy for eradication of Helicobacter pylori infection usually lasts for 7 days and can be extended to a maximum of 2 weeks. The duodenal ulcer heals completely within 2 weeks. If a two week treatment period is not sufficient, healing will be achieved in almost all cases within a further 2 weeks.
Gastric ulcers and reflux oesophagitis usually require a 4 week course of treatment. If this should be inadequate, healing will in most cases be achieved within a further 4 weeks.
Treatment should not exceed 8 weeks as experience with long term use is limited. The daily dose of 40 mg should not be exceeded in elderly patients or in patients with impaired kidney function. An exception is combination therapy for eradication of Helicobacter pylori, where also elderly patients should receive the appropriate dose, 40 mg twice daily, during 1 week treatment.

CONTRA-INDICATIONS:
Tropizol is contra-indicated in patients with known hypersensitivity to any component of this product.

PRECAUTIONS & WARNINGS:
General:
Pantoprazole is not indicated for mild gastrointestinal complaints, e.g. nervous stomach. In the case of combination therapy, the prescribed information for the respective drugs must be observed. Before giving pantoprazole to patients with gastric ulcers the possibility of malignancy should be considered since pantoprazole may mask symptoms and delay diagnosis. A diagnosis of reflux esophagitis should be confirmed by endoscopy.
Pantoprazole is extensively metabolized in the liver and some sources recommend that dose should be reduced in hepatic impairment.

Information for patient:
Patient should be cautioned that **Tropizol** tablets should not be split, crushed or chewed. The tablets should be swallowed whole, with or without food in the stomach. Concomitant administration of antacids does not affect the absorption of pantoprazole.

PREGNANCY / LACTATION:
Tropizol should be given with caution in Pregnancy/Lactation only if the potential benefit justifies the potential risk to the fetus.

PEDIATRIC USE:
Safety and Effectiveness in pediatric patients have not been established.

ELDERLY PATIENTS:
In clinical studies, no overall difference in safety or effectiveness was observed between elderly and younger patients.

DRUG INTERACTIONS:
Pantoprazole may reduce the absorption of drugs whose bioavailability is pH dependent (e.g. Ketokonazole). Pantoprazole is metabolized through the cytochrome P450 system, primarily the CYP2C19 and CYP3A4 isoenzymes, and subsequently undergoes Phase II conjugation. Based on interactions of pantoprazole with other drugs, no dosage adjustment is needed with concomitant use of following: theophylline, cisapride, antipyrine, caffeine, carbamazepine, diclofenac, digoxin, diazepam, glyburide, nifedipine, phenytoin, metronidazole, warfarin, clarithromycin, or amoxicillin. Relevant interactions of pantoprazole with other drugs with the same metabolic pathways are not expected. Therefore, when co-administration with pantoprazole, adjustments of the dosage of pantoprazole or of such drugs may not be necessary. There is also no interaction with concomitantly administered antacids.

SIDE EFFECTS:
Pantoprazole has been well tolerated in both short term and long term therapy. Most frequent adverse effects include headache, diarrhea, flatulence, abdominal pain, rash, eructation, insomnia, hyperglycemia, liver function tests abnormal, nausea, and vomiting.
Adverse effects in isolated cases include anxiety, back pain, chest pain, bronchitis, constipation, cough increased, dizziness, dyspepsia, dyspnea, flu syndrome, gastroenteritis, gastrointestinal disorder, neck pain, rhinitis, sinusitis, urinary tract infection, upper respiratory infection, and pharyngitis.

OVER DOSAGE:
In case of overdosage, treatment should be symptomatic and supportive.

STORAGE CONDITIONS:
* Store in a cool and dry place.
* Protect from heat, direct sunlight and moisture.

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