Front

zotonix®

(PANTOPRAZOLE)

40 mg
Tablet

ذوٹونِکس

COMPOSITION:
Each enteric coated tablet contains:
Pantoprazole Sodium Sesquihydrate
USP equivalent to Pantoprazole ..... 40 mg.

Product Specs.: USP

INDICATIONS:
Moderate and severe cases of inflammation of the oesophagus (reflux oesophagitis). In combination with two appropriate antibiotics (see Dosage) for the eradication of Helicobacter pylori in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism.
Duodenal ulcer
Gastric ulcer
Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions.

CONTRAINDICATIONS:
Zotonix must not be used in combination treatment for eradication of Helicobacter pylori in patients with moderate to severe liver or kidney function disturbances since currently no clinical data are available on the efficacy and safety of **Zotonix** in combination treatment of these patients. **Zotonix** should generally not be used in cases of known hypersensitivity to one of the constituents of Zotonix or of the combination partners. Pantoprazole, like other PPIs, should not be co-administered with atazanavir. Special warnings and precautions for use of **Zotonix** are not indicated for mild gastrointestinal complaints, e.g. nervous stomach. In the case of combination therapy, the prescribing information for the respective drugs must be observed. Prior to treatment the possibility of malignancy of gastric ulcer or a malignant disease of the oesophagus should be excluded as the treatment with Pantoprazole may alleviate the symptoms of malignant ulcers and can thus delay diagnosis. In the presence of any alarming symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis, anaemia or melaena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with Pantoprazole may alleviate symptoms and delay diagnosis. Further investigation is to be considered if symptoms persist despite adequate treatment. In patients with Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions requiring long-term treatment, Pantoprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo-or achlorhydria. This should be considered if respective clinical symptoms are observed.

PREGNANCY AND LACTATION:
There is no information on the excretion of Pantoprazole into human breast milk. **Zotonix** tablets should only be used when the benefit to the mother is considered greater than the potential risk to the foetus/baby.
Effects on the ability to drive and use machines: There are no known effects on the ability to drive and use machinery.

INTERACTIONS:
Pantoprazole may reduce the absorption of drugs whose bioavailability is pH-dependent (e.g. ketoconazole) it has been shown that co-administration of atazanavir 300 mg / ritonavir 100 mg with omeprazole (40 mg once daily) or atazanavir 400 mg with lansoprazole (60mg single dose) to healthy volunteers resulted in a substantial reduction in the bioavailability of atazanavir. The absorption of atazanavir is pH dependent. Therefore PPIs, including Pantoprazole, should not be co-administered with atazanavir. Please note that this information also applies to drugs which you might have used recently.
Pantoprazole is metabolized in the liver via the cytochrome P450 enzyme system. An interaction with other drugs or substances metabolized by the same enzyme system cannot be ruled out. However, in targeted studies involving a range of such drugs and substances no clinically significant interactions were observed; studies have been carried out on carbamapepine, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, nifedipine, phenytoin, theophylline, and an oral contraceptive. There were also no interactions with concomitantly administered antacids. Although no interaction during concomitant administration of phenprocoumon or warfarin has been observed in clinical pharmacokinetic studies, a few isolated cases of changes in INR have been reported during concomitant treatment in the post-marketing period. Therefore in patients being treated with coumarin anticoagulants monitoring of prothrombin time / INR is recommended after initiation, termination or during irregular use of Pantoprazole. Please make sure to inform your doctor if you are taking drugs affecting blood coagulation. Additional checks of your blood coagulation values may be necessary. No interactions were observed with the respective antibiotics (clarithromycin, metronidazole, amoxicillin).

DOSAGE AND METHOD OF ADMINISTRATION:
Adults & adolescents 12 years of age & above:
For duodenal ulcer, gastric ulcer, and reflux oesophagitis: Generally, 1 gastro-resistant tablet daily. In individual cases the dose may be doubled (increase to 2 gastro-resistant tablets per day), particularly when there has been no response to other medicines.
Adults: In cases of duodenal or gastric ulcer in which infection with Helicobacter pylori has been confirmed, the microorganism should be eradicated by combination treatment.

Back

Depending on the resistance pattern, the following combinations are recommended:

a)	2 x 1 Zotonix gastro-resistant tablet / day	+ 2 x 1000 mg amoxicillin / day + 2 x 500 mg clarithromycin / day
b)	2 x 1 Zotonix gastro-resistant tablet / day	+ 2 x 500 mg metronidazole / day + 2 x 500 mg clarithromycin / day
c)	2 x 1 Zotonix gastro-resistant tablet / day	+ 2 x 1000 mg amoxicillin / day + 2 x 500 mg metronidazole / day

If combination therapy is not an option, e.g. if the patient has tested negative for Helicobacter pylori, the following dosage guidelines apply for
Pantoprazole monotherapy:
Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions. For the long-term management of Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions patients should start their treatment with a daily dose of 80mg (2 tablets of Zotonix 40 mg). Thereafter, the dosage can be titrated up or down as needed using measurements of gastric acid secretion to guide. With doses above 80mg daily, the dose should be divided and given twice daily. A temporary increase of the dosage above 160 mg Pantoprazole is possible but should not be applied longer than required for adequate acid control. Treatment duration in Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions is not limited and should be adapted according to clinical needs. In patients with severe liver impairment the dose has to be reduced to 1 tablet (40 mg Pantoprazole) every other day. Furthermore, in these patients the liver enzymes should be monitored during Pantoprazole therapy. In the case of a rise of the liver enzymes, **Zotonix** should be discontinued. The daily dose of 40 mg Pantoprazole 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 Pantoprazole dose (2x40 mg per day) during the 1 week treatment period.

TYPE AND DURATION OF TREATMENT:
Combination therapy for eradication of Helicobacter pylori infection usually lasts 7 days and can be extended to a maximum of 2 weeks. If after this time further treatment with Zotonix is indicatd to ensure that the ulcer heals completely, the dose recommendations for gastric and duodenal ulcers must be observed. In the majority of cases, a 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.

INSTRUCTIONS FOR USE / HANDLING:
Zotonix gastro-resistant tablets must not be chewed or crushed and must be swallowed whole with water 1 hour before breakfast. In combination therapy for eradication of Helicobacter pylori infection the second Zotonix tablet should be taken before the evening meal.

OVERDOSE:
There are no known symptoms of overdosage in man. Doses up to 240 mg I.V. were administered over 2 minutes and were well tolerated. In the case of overdosage with clinical signs of intoxication, the usual rules of intoxication therapy apply.

UNDESIRABLE EFFECTS:
Treatment with Zotonix can occasionally lead to headache, gastrointestinal complaints such as upper abdominal pain, diarrhea, constipation or flatulence, as well as allergic reactions such as itching, skin rash and, in isolated cases, wheals, mucosal swelling or anaphylactic reactions including anaphylactic shock with typical symptoms such as dizziness, increased pulse rate or increased perspiration. There have been rare reports of nausea, dizziness, visual disturbances (blurred vision). In isolated case, swelling of the lower arms and legs, fever and muscular pain were observed which disappeared after discontinuation of Pantoprazole. Depression, hallucination, disorientation and confusion, especially in pre-disposed patients, as well as the aggravation of these symptoms in case of pre-existence has also been reported. Vomiting, dry mouth, leukopenia (reduction in number of white blood cells), thrombocytopenia (reduction in number of blood platelets), arthalgia (pain in joints).
Severe hepatocellular damage leading to jaundice with or without hepatic failure.
Increased liver enzymes (transaminases, r-GT, elevated triglycerides).
Interstitial nephritis, Lyell Syndrome.
Severe skin reactions such as Stevens-Johnson-Syndrome, erythema multiforme, photosensitivity.
If you experience any side effects not mentioned in this package leaflet, please inform your doctor or pharmacist.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

PRESENTATION:
Zotonix Tablet 40 mg : Pack of 2 x 7 tablets.

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL
Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
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