PANTOVER® 40 mg

Active ingredient : Pantoprazol sodium sesquihydrate

Composition
Active ingredient
1 Enteric coated tablet contains:
Pantoprazole sodium sesquihdrate 45.1 mg (corresponding to 40 mg Pantprazole) .

Excipients
Sodium carbonat anhydrous; mannitol ;crospovidone ;povidon ; calcium stearate ; Ethanol 96% ; Opadry II white Powder : Acryl-EZE yellow Powder : Simethicone Emulsion .

Pharmaceutical form and contents
Enteric coated tablets ..... Pack with 14 tablets , pack with 15 tablets , pack with 30 tablets

Pharmacotherapeutic / indication group / action mechanism
Selective Proton pump inhibitor . substituted benzimidazole .

Manufacturer : Jordan River Pharmaceutical Industries (L.L.C)

Indications
- In combination with two appropriate antibiotics (see " posology ") 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
- Moderate and severe cases of inflammation of the esophagus (reflux esophagitis) .
- Zollinger -Ellison -Syndrome and other pathological hypersecretory conditions .

Contraindications
Pantover 40 mg 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 pantover 40 mg in combination treatment of these patients .
Pantover 40 mg should generally not be used in cases of known hypersensitivity to one of the constituents of Pantover 40 mg or of the combination partners .

Special warnings and precautions for use
Pantover 40 mg is not indicated for mild gastrointestinal complaints e.g. nervous stomach .In the case of combination therapy, the prescribing informations for the respective drugs must be observed. Prior to treatment with Pantover 40 mg steps must be taken to ensure that the gastric ulcer is not malignant, and that there is no malignant disease in the esophagus, since the treatment would also alleviate the complaints associated with malignant diseases and possibly delay establishment of the diagnosis .
A diagnosis of reflux esophagitis should be confirmed by endoscopy to date there has been no experience with treatment in children. 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 (cyano- cobalamin) due to hypo- or achlorhydria . This should be considered if respective clinical symptoms are observed .

pregnancy and lactation
Clinical experience in pregnant women is limited . There is no information on the excretion of pantoprazole into human breast milk. pantover 40 mg 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 to use machines or work without a firm foothold .
There are no known effects on the ability to drive or to operate machinery or work without a firm foothold.

Interactions
Pantover 40 mg may reduce the absorption of drugs whose bioavailability is pH-dependent (e.g . Ketoconazole) .
Please note that this information also applies to drugs which you might have used recently . The active ingredient of Pantover 40 mg 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 carbamazepine , caffiene , diazepam , diclofenac , digoxin , ethanol , glibenclamide , metoprolol , naproxen , nifedipine , pahenprocoumon , phenytoin , piroxicam , theophylline , warfarin , and an oral contraceptive . There were also no interactions with concomitantly administered antacids . No clinically relevant interactions were observed with the respective antibiotics [clarithromycin, metronidazole , amoxicillin) .

Posology and method of administration
The following information applies unless Pantover 40 mg has been otherwise prescribed by your doctor .Please Follow these instructions as otherwise Pantover 40 mg may not have the desired effect . In cases of duodenal or gastric ulcer in which infection with Helicobacter pylori has been confirmed , the microorganism should be eradicated by combination treatment . depending on the resistance pattern , the following combinations are recommended :

a) 2 * 1 Pantover 40 mg enteric coated tablet / day
+ 2 * 1000 mg amoxicillin / day
+ 2 * 500 mg clarithromycin / day

b) 2 * 1 Pantover 40 mg enteric coated tablet / day
+ 2 * 500 mg metronidazole / day
+ 2 * 500 mg clarithromycin / day

c) 2 * 1 Pantover 40 mg enteric coated tablet / day
+2 * 1000 mg amoxicillin / day
+2 * 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 Pantover 40 mg monotherapy : For duodenal ulcer , gastric ulcer , and reflux esophagitis :
Generally , 1 Pantover 40 mg enteric coated tablet daily . In individual cases the dose may be doubled (increase to 2 Pantover 40 mg gastro-resistant tablet per day) , particularly when there has been no response to other medicines .
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 Pantover 40 mg therapy . In the case of a rise of the liver enzymes , Pantover 40 mg should be discontinued .

The daily dose of 40mg 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 (2 * 40 mg per day) during the 1-week treatment period .
For the long-term management of Zollinger -Ellison - Syndrome and other pathological hypersecretory conditions the recommended daily dose at the beginning of the treatment is 80 mg (2 tablets of pantover 40 mg) . Thereafter , the dosage can be titrated up or down as needed using measurements of gastric acid secretion to guide . With doses above 80 mg 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 .

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 Pantover 40 mg is indicated 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 esophagitis usually require a 4-weeks course of treatment . If this should be inadequate , healing will in most cases be achieved within a further 4 weeks .Treatment duration in Zollinger - Ellison - Syndrome and other pathological hypersecretory conditions is not limited and should be adapted according to clinical needs . Except for patients with Zollinger -Ellison - Syndrome and other pathological hypersecretory conditions , the duration of treatment with the active ingredient pantoprazole should not exceed 8 weeks as experience with long-term-treatments is limited .

Instructions for use / handling
pantover 40 mg enteric coated tablets must not be chewed or crushed and must be swallowed whole with water 1 h before breakfast .In combination therapy for eradication of Helicobacter pylori infection the second pantover 40 mg tablet should be taken before the evening meal .

Incorrect use and overdosage
There are no Known smyptoms of overdosage in man ; in any case , the doctor must be consulted . In the case of overdosage with clinical signs of intoxication , the usual rules of intoxication apply .If you have taken too little pantover 40 mg or have forgotten to take it do not take the dose late, but continue with the next regular dose on your dosing schedule . Talk to your doctor if you want to interrupt or prematurely discontinue treatment with pantover 40 mg .

undesirable effects
See table below .
If you experience any side effects not mentioned in this leaflet , please inform your doctor or pharmacist .

Countermeasures
If you should experience side effects , notify your doctor so that he can decide what further measures are necessary .

Storage conditions and shelf life
pantover 40 mg enteric coated tablets stored below 30 °C remain unchanged for 2 years .
The expiry date of this pack is printed on the container and on the folding box .
Do not use this pack after the expiry date !
Date of last revision of the text

Augest 2007
Keep out of the reach of children !

Table Undesirable effects

Frequency / Organ System	Common (≥1 / 100, ≤ 1 / 10)	Uncommon (≥1 / 1,000, ≤ 1 / 100)	very rare (≤1 / 10,000,incl. isolated reports)
Gastrointestinal disorders	Upper abdominal pain, diarrhoea, nausea, vomiting, flatulence, constipation, dry mouth	Nausea	
General disorders and administration site conditions			peripheral edema
Hepatobiliary disorders			Severe hepatocellular damage leading to jaundice with or without hepatic failure
Immune system disorders			Anaphylactic reactions including anaphylactic shock with its typical symptoms such as dizziness, rapid pulse, or profuse sweating
Investigations			Increased liver enzymes (transaminases, GT), elevated triglycerides, increased bilirubin concentrations
Musculoskeletal,connective tissue disorders			Myalgia
Nervous system disorders	Headache	Dizziness, disturbances in vision (blurred vision)	
Psychiatric disorders			Mental depression
Renal and urinary disorders			Interstitial nephritis
Skin and subcutaneous tissue disorders		Allergic reactions such as pruritus and skin rash	Urticaria, swelling of the skin or mucous membranes ; angioedema , severe reactions of the skin and mucous membranes, often associated with blistering, with target lesions (Stevens-Johnson syndrome, erythema multiforme, exudative skin syndrome, Lyell's syndrome)), increased sensitivity to light (photosensitivity)

This is a medicament:
- A medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the metod of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine , its benefits and risks .
- Do not by yourself interrupt the period of treatment prescribed for you .
- Do not repeat the same prescription without consulting your doctor .
- Keep out of reach of children .

Council of Arab Health Ministers
Union of Arab Pharmacists