



# Pantomax® 40 mg

## Pantoprazole

### Composition:

#### Active ingredient

Each enteric coated tablet contains 45.1 mg Pantoprazole Sodium Sesquihydrate equivalent to 40 mg Pantoprazole.

### Pharmacotherapeutic / indication group / action mechanism

Selective proton pump inhibitor, substituted benzimidazole .

### 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 micro-organism.
- Duodenal ulcer
- Gastric ulcer
- Moderate and severe cases of inflammation of the esophagus (reflux esophagitis).

### Contraindications

PANTOMAX® 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 PANTOMAX® 40 mg in combination treatment of these patients.

PANTOMAX® 40 mg should generally not be used in cases of known hypersensitivity to one of the constituents of Pantomax 40 mg or of the combination partners.

### Special warnings and precautions for use

PANTOMAX® 40 mg is 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 with PANTOMAX® 40 mg steps must be taken to ensure that the gastric ulcer is not malignant, and that there is no malignant disease in the oesophagus, 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.

### Pregnancy and Lactation

Clinical experience in pregnant women is limited. There is no information on the excretion of pantoprazole into human breast milk. PANTOMAX® 40 mg tablets should only be used when the benefit to the mother is considered greater than the potential risk to the fetus/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 to work without a firm foothold.

### Interactions

PANTOMAX® 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 ingredients of PANTOMAX® 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, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, nifedipine, phenprocoumon, phenytoin, 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 PANTOMAX® 40 mg has been otherwise prescribed by your doctor. Please follow these instructions, as otherwise PANTOMAX® 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:

- 2x1 PANTOMAX® 40 mg gastro-resistant tablet / day  
+ 2 x 1000 mg amoxicillin / day  
+ 2 x 500 mg clarithromycin / day
- 2x1 PANTOMAX® 40 mg gastro-resistant tablet / day  
+ 2 x 500 mg metronidazole / day  
+ 2 x 500 mg clarithromycin / day
- 2 x 1 PANTOMAX® 40 mg 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 PANTOMAX® 40 mg monotherapy:

For duodenal ulcer, gastric ulcer, and reflux oesophagitis:

Generally, 1 PANTOMAX® 40 mg gastro-resistant tablet daily.

In individual cases the dose may be doubled (increase to 2 PANTOMAX® 40 mg gastro-resistant tablets 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 PANTOMAX® 40 mg therapy. In the case of a rise of the liver enzymes, PANTOMAX® 40 mg should be discontinued.

The daily dose of 40 mg pantoprazole should not be exceeded in elderly 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 x 40 mg per day) during the 1-week treatment period.

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 PANTOMAX® 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 oesophagitis usually require a 4-week course of treatment. If this should be inadequate, healing will be in most cases be achieved within a further 4 weeks.

Treatment should not exceed 8 weeks as experience with long-term use is limited.

### Instructions for use / handling

PANTOMAX® 40 mg 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 PANTOMAX® 40 mg tablet should be taken before the evening meal.

### Incorrect use and overdose

If you have taken too little PANTOMAX® 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 PANTOMAX® 40 mg. There are no known symptoms of overdose in man; in any case, the doctor must be consulted. In the case of overdose with clinical signs of intoxication, the usual rules of intoxication therapy apply.

### Undesirable effects

Treatment with PANTOMAX® 40 mg 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 shock with typical symptoms such as dizziness, increased pulse rate or increased perspiration.

There have been rare reports of nausea, dizziness, and visual disturbances (blurred vision).

In isolated cases, swelling of the lower arms and legs, fever, depression and muscular pain were observed which disappeared after discontinuation of Pantoprazole 40 mg.

If you experience any side effects not mentioned in this package 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

Stored below 30°C.

Do not use this pack after the expiry date!

### Presentation

Packs of 15, 30 enteric coated tablets: Each enteric coated tablet contains 45.1 mg Pantoprazole Sodium Sesquihydrate equivalent to 40 mg Pantoprazole.

### THIS IS A MEDICAMENT

- A drug is a product which acts on your health and its consumption could be dangerous when you do not follow the instructions.
- Follow strictly the doctor's prescriptions, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist know the 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 the reach of children.

Manufactured by : **SAJA Pharmaceuticals Co., Ltd.**

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