NYCOMED

Instructions for Use

Pantozol® 20 mg

Active ingredient: Pantoprazole sodium sesquihydrate

Composition
One gastro-resistant tablet contains

Active ingredient

Pantoprazole sodium sesquihydrate 22.6 mg
(equivalent to pantoprazole 20 mg)

Excipients

Sodium carbonate; mannitol (corresp. to 0.0018 BU); crospovidone; povidone K90; povidone K 25; calcium stearate; propylene glycol; hypromellose; methacrylic acid-ethylacrylate-copolymer (1:1); polysorbate 80; sodium lauryl sulphate; triethyl citrate; colours (E 171 and E 172); printing ink

Pharmaceutical form and contents
Gastro-resistant tablets
Packs with 7, 15 and 30 tablets
(Note: possibly not all pack sizes available in each country)

Pharmacotherapeutic / indication group / action mechanism
Selective proton pump inhibitor, substituted benzimidazole

Holder of the marketing authorization / Manufacturer
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Indications
For the treatment of mild gastroesophageal reflux disease and associated symptoms (e.g. heartburn, acid regurgitation, pain on swallowing).

For long-term management and prevention of relapse in reflux oesophagitis.

Prevention of gastroduodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAID treatment (see section "Precautions for use and warnings").

Contraindications
Pantozol 20 mg must not be used in cases of known hypersensitivity to the active ingredient or/and any of the other constituents of Pantozol 20 mg.

Special warnings and precautions for use
In patients with severe liver impairment the liver enzymes should be monitored regularly during treatment with pantoprazole, particularly on long-term use. In the case of a rise of the liver enzymes Pantozol 20 mg should be discontinued.

Prior to treatment a malignant disease of the esophagus or stomach should be excluded as the treatment with pantoprazole may alleviate the symptoms of malignant diseases and can thus delay diagnosis.

Patients who do not respond after 4 weeks should be investigated.

To date there has been no experience with treatment in children.

The use of Pantozol 20 mg as a preventive of gastroduodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) should be restricted to patients who require continued NSAID treatment and have an increased risk to develop gastrointestinal complications.

The increased risk should be assessed according to individual risk factors, e.g.high age (>65 years), history of gastric or duodenal ulcer or upper gastrointestinal bleeding.

Pantoprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy.

Pregnancy and lactation

Clinical experience in pregnant women is limited. There is no information on the excretion of pantoprazole into human breast milk. Pantozol 20 mg gastro-resistant 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 to work without a firm foothold.

THIS IS A MEDICAMENT

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

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Interactions
Pantozol 20 mg may reduce or increase 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.

Pantoprazole is metabolized in the liver via the cytochrome P450 enzyme system. An interaction of pantoprazole with other drugs or compounds which are metabolized using the same enzyme system cannot be excluded. However, no clinically significant interactions were observed in specific tests with a number of such drugs or compounds, namely carbamazepine, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, naproxen, nifedipine, phenprocoumon, phenytoin, piroxicam, theophylline, warfarin and an oral contraceptive.

There were also no interactions with concomitantly administered antacids.

Dosage and method of administration
Unless otherwise prescribed, the following oral doses apply. Please follow these instructions, otherwise there is the risk that the drug may not act properly!

Mild gastroesophageal reflux disease and associated symptoms (e. g. heartburn, acid regurgitation, pain on swallowing)
The recommended oral dosage is one gastro-resistant tablet Pantozol 20 mg per day.

Long-term management and prevention of relapse in reflux oesophagitis
For long-term management, a maintenance dose of one gastro-resistant tablet Pantozol 20 mg per day is recommended, increasing to 40 mg pantoprazole per day if a relapse occurs. Pantozol 40 mg is available for this case. After healing of the relapse the dosage can be reduced again to 20 mg pantoprazole.

Prevention of gastroduodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAID treatment.
The recommended oral dosage is one gastro-resistant coated tablet Pantozol 20 mg per day.

Note
A daily dose of 20 mg pantoprazole should not be exceeded in patients with severe liver impairment.
No dose adjustment is necessary in elderly patients or in those with impaired renal function.

Type and duration of treatment
Mild gastroesophageal reflux disease and associated symptoms (e. g. heartburn, acid regurgitation, pain on swallowing)

Symptom relief is generally accomplished within 2-4 weeks, and a 4 week treatment period is usually required for healing of associated oesophagitis. If this is not sufficient, healing will usually be achieved within a further 4 weeks.

Long-term management and prevention of relapse in reflux oesophagitis

In long-term treatment, a treatment period of 1 year should be exceeded only after careful consideration of the benefit / risk ratio, as drug safety over several years is not sufficiently established.

Instructions for use / handling
Pantozol 20 mg gastro-resistant tablets should not be chewed or crushed, and should be swallowed whole with liquid before a meal.

Incorrect use and overdosage
There are no known symptoms 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 therapy apply.
If you have taken too little Pantozol 20 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 Pantozol 20 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
Pantozol 20 mg gastro-resistant tablets stored at room temperature remain unchanged for 3 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
December 2003

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; constipation; flatulence	Nausea	
General disorders and administration site conditions			Peripheral edema subsiding after termination of therapy
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 (transminases, γ - GT); elevated triglycerides; increased body temperature subsiding after termination of therapy
Musculoskeletal, connective tissue disorders			Myalgia subsiding after termination of therapy
Nervous system disorders	Headache	Dizziness; disturbances in vision (blurred vision)	
Psychiatric disorders			Mental depression subsiding after termination of therapy
Renal and urinary disorders			Interstitial nephritis
Skin and subcutaneous tissue disorders		Allergic reactions such as puritus 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, scalded skin syndrome (Lyell's syndrome)); increased sensitivity to light (photosensitivity)