
PATIENT INFORMATION LEAFLET
PANTOLOC RANGE

Read all of this leaflet carefully before you start taking PANTOLOC®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **PANTOLOC®** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

S4

PANTOLOC® 20 Enteric-coated tablets

PANTOLOC® 40 Enteric-coated tablets

PANTOLOC® IV Lyophilised powder for injection

WHAT PANTOLOC® CONTAINS

- The active substance:

PANTOLOC® 20 - Each tablet contains 20 mg pantoprazole and is sugar-free.

PANTOLOC® 40 - Each tablet contains 40 mg pantoprazole and is sugar-free.

PANTOLOC® IV - Each vial contains 40 mg pantoprazole.

- The other ingredients are:

Tablets - calcium stearate, crospovidone, hypromellose, mannitol, methacrylic acidethylacrylate-copolymer (1:1), polysorbate 80, povidone K25, povidone K90, propylene glycol, sodium carbonate, sodium laurilsulphate, titanium dioxide E171, triethyl citrate, yellow ferric oxide.

The tablet-marking contains small amounts of the following: shellac, iron oxides, soya lecithin, titanium dioxide E171 and antifoam DC1510.

IV – edetate disodium dehydrate and sodium hydroxide

WHAT PANTOLOC® IS USED FOR

PANTOLOC® is used to treat certain conditions in which there is too much acid in the stomach. It is used to

treat duodenal and gastric ulcers, reflux oesophagitis and Zollinger-Ellison Syndrome. It is indicated for symptomatic improvement (e.g. heartburn, contents of the stomach which washes back into the oesophagus, pain on swallowing) and healing of mild gastro-oesophageal reflux disease. **PANTOLOC®** is indicated for the prevention of gastroduodenal lesions, heartburn and indigestion symptoms caused by non-selective non-steroidal anti-inflammatory drugs (NSAID's), i.e medicines other than cortisone used to treat pain and inflammation. **PANTOLOC®** works by decreasing the amount of acid produced by the stomach.

BEFORE YOU TAKE PANTOLOC®

Do not take PANTOLOC®:

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients.
- if you are taking atazanavir (an anti-HIV medicine)
- if you have serious liver problems

PANTOLOC® IV is only for intravenous use.

Take special care and consult your doctor:

- if you have regularly been taking any acid-blocking medicines over a long period of time (e.g. longer than 3 years)
- if you are taking tablets containing ketoconazole, used to treat fungal infections of the skin and nails. This is because **PANTOLOC®** may increase or decrease the effect of ketoconazole by altering the amount that gets in your body.
- if you are taking Vitamin B12 supplements
- if you think you have signs of stomach cancer. These include persistent weight loss, dark stools, loss of appetite, feeling full or a lump in your stomach.
- If you experience severe and/or persistent diarrhoea, as **PANTOLOC®** has been associated with a small increase in infectious diarrhoea.

Elderly patients

PANTOLOC® has not been shown to cause different side effects or problems in older people than it does in younger adults.

Kidney and liver disease

No dosage adjustment is required in the presence of kidney disease.

A daily dose of not more than 20 mg is advised if you have liver disease.

Pregnancy and breast feeding:

Safety in pregnancy and during breastfeeding has not been established. If you are pregnant or breastfeeding your baby while taking **PANTOLOC**[®], please consult your doctor, pharmacist or other healthcare professional for advice.

Taking PANTOLOC[®] with food and drink:

PANTOLOC[®] tablets may be taken with food or on an empty stomach.

PANTOLOC[®] IV is given intravenously and is not affected by food or drink.

Taking other medicines with PANTOLOC[®]:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, consult your doctor, pharmacist or other healthcare professional for advice, as these medicines may cause undesirable interactions. Other medicines that reduce stomach acid can be taken at the same time as **PANTOLOC**[®].

Some of the medicines that can be affected by taking **PANTOLOC**[®] include: Medicines to thin your blood, such as warfarin. **PANTOLOC**[®] may alter the effect of these medicines so your doctor may monitor how well your blood clots.

PANTOLOC[®] may decrease the amount of atazanavir, which is used for the treatment of HIV infection, that gets into your body.

PANTOLOC[®] may increase the levels of methotrexate (high doses used in the treatment of certain cancers) and possibly lead to methotrexate toxicities.

HOW TO TAKE PANTOLOC®**Tablets:**

Always take **PANTOLOC®** exactly as your doctor has instructed. Check with your doctor or pharmacist if you are unsure. The once daily dose of **PANTOLOC®** should be taken in the morning. The tablet should be swallowed whole with a little water either before or during breakfast. Do not crush, break or chew the tablet.

IV:

PANTOLOC® IV is given to patients who cannot take oral medication.

Your doctor or healthcare professional will administer **PANTOLOC® IV** for you. The recommended dose is one vial of **PANTOLOC® IV** per day.

Your doctor or healthcare professional will prepare the injection for you and administer it over 2 to 15 minutes. As soon as oral therapy is possible, your doctor will change over from intravenous to oral medication.

**Duodenal ulcer**

PANTOLOC® tablets: The recommended dose is **40 mg PANTOLOC®** once daily for 2 to 4 weeks.

PANTOLOC® IV: The recommended dose is one vial of **PANTOLOC® IV** per day. The total treatment with IV and oral **PANTOLOC®** should be for 2 to 4 weeks. If the duodenal ulcer is associated with a *Helicobacter pylori* infection, **PANTOLOC® IV** can be given while you are taking the antibiotic medication.

Gastric ulcer and reflux oesophagitis

The recommended dose is one **40 mg PANTOLOC® tablet** or one vial of **PANTOLOC® IV** per day for 4 to 8 weeks.

Zollinger-Ellison Syndrome

The starting dose is usually one **40 mg PANTOLOC®** tablet taken twice daily or one vial of **PANTOLOC® IV** taken twice daily. Your doctor will advise you on how to take the medicine.

Mild gastro-oesophageal reflux disease

The dose is one **20 mg PANTOLOC®** tablet per day for 4 to 8 weeks. In patients with healed reflux disease, re-occurring symptoms can be controlled using **20 mg PANTOLOC®** when needed.

Long-term treatment and to prevent gastro-oesophageal reflux disease starting up again

For a long period of treatment a dose of one **20 mg PANTOLOC®** tablet per day is advised, increasing to one **40 mg PANTOLOC®** tablet per day if the **gastro-oesophageal reflux disease** starts again. After healing, the dose can once again be reduced to 20 mg daily.

One **20 mg PANTOLOC®** tablet per day can be taken together with certain anti-inflammatory medicines, to prevent heartburn, indigestion and possible injury to the stomach and intestines.

If you take more PANTOLOC® than you should:

In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take PANTOLOC®:

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten doses.

POSSIBLE SIDE EFFECTS

PANTOLOC® can have side effects.

Check with your doctor as soon as possible if any of the following side effects occur:

Abdominal or stomach pain, diarrhoea, blistering, loosening, peeling or redness of the skin, skin rash, hives or itching; sudden loss of vision, nausea, vomiting, pain in joints, dry mouth.

Check with your doctor if any of the following side effects worry you:

Headache, constipation, flatulence, muscle pains, anxiety, back pain, blurred vision, dizziness, chills, confusion, distortion or complete lack of a sense of taste, a reduction in the number of white blood cells (which may lead to frequent infections) or red blood cells.

Some side effects may disappear during treatment as your body adjusts to the medicine. These do not need medical attention.

Not all side effects reported for **PANTOLOC®** are included in this leaflet. Should your general health worsen while taking **PANTOLOC®**, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF PANTOLOC®

Store at or below 25 °C.

Protect the medicine from light and moisture.

Do not store in the bathroom.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist for correct disposal.

Do not throw unused medicine down drains or toilets.

KEEP OUT OF REACH OF CHILDREN

PRESENTATION OF PANTOLOC®

PANTOLOC® 20: blister packs of 28 tablets.

PANTOLOC® 40: blister packs of 14 and 28 tablets.

PANTOLOC® IV: A vial containing dry powder (1 x 5 vials).

IDENTIFICATION OF PANTOLOC®

PANTOLOC® 20: Yellow, oval, biconvex enteric-coated tablet with a white to off-white core, imprinted "P20" on one side.

PANTOLOC® 40: Yellow, oval, biconvex enteric-coated tablet, with a white to off-white core, imprinted "P40" on one side.

PANTOLOC® IV: A white to almost white dried powder in a glass vial for injection. A clear yellowish solution forms once the powder is mixed with solution.

REGISTRATION NUMBER

PANTOLOC® 20: 34/11.4.3/0005

PANTOLOC® 40: 28/11.4.3/0407

PANTOLOC® IV: 33/11.4.3/0041

NAME AND ADDRESS OF REGISTRATION HOLDER

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DATE OF PUBLICATION

25 April 2013

Namibia:

Pantoloc 20 – 05/11.4.3/0395

Pantoloc 40 – 05/11.4.3/0396

Pantoloc IV – 05/11.4.3/0397