

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pantoprazol Combino Pharm 40 mg powder for solution for injection Pantoprazol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pantoprazol Combino Pharm 40 mg powder for solution for injection is and what it is used for
2. What you need to know before you use Pantoprazol Combino Pharm 40 mg powder for solution for injection
3. How to use Pantoprazol Combino Pharm 40 mg powder for solution for injection
4. Possible side effects
5. How to store Pantoprazol Combino Pharm 40 mg powder for solution for injection
6. Contents of the pack and other information

1. WHAT Pantoprazol Combino Pharm 40mg Powder for Solution for injection IS AND WHAT IT IS USED FOR

Pantoprazole belongs to a group of medicines called proton pump inhibitor, that reduces the production of stomach acid. It is indicated for treatment of duodenal ulcer, gastric ulcer, moderate and severe esophagitis and other illness with an hypersecretory conditions increased, as Zollinger-Ellison-Syndrome.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE Pantoprazol Combino Pharm 40mg Powder for Solution for injection

Do not use Pantoprazol Combino Pharm 40mg Powder for Solution for injection

- if you are allergic to Pantoprazole or any of the other ingredients of this medicine (listed in section 6).

Take special care with Pantoprazol Combino Pharm 40mg Powder for Solution for injection

- if you suffer from a liver disorder or a kidney disorder, please tell your doctor who will decide whether your dose has to be adjusted.

If the above statement applies to you, please talk to your doctor.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pantoprazol Combino Pharm 40mg may increase or decrease the absorption of the other medicines by decreasing the acidity stomach, such as Ketoconazol.

Please tell your doctor if you are taking medicines to thin your blood (oral anticoagulants) such as warfarin or phenprocoumon, so your doctor could monitored with additional test.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.
Consult with your doctor if you are pregnant or think you may be pregnant, or if you are breast-feeding, before taking the treatment. Your doctor could value the convenient or not to use this medicine.

Driving and using machines

It has not been described effects on the ability to drive and use machines.

3. HOW TO USE Pantoprazol Combino Pharm 40mg Powder for Solution for injection

Pantoprazol Combino Pharm 40mg is only administered in a hospital for professional healthcare. This medicine will be administered for intravenous use.

Your doctor will indicate the duration of the treatment with Pantoprazol Combino Pharm 40mg.

To treat duodenal ulcer, gastric ulcer and moderate and severe reflux esophagitis, the recommended dosage is 1 vial per day (40 mg). As soon as oral therapy is possible, treatment with Pantoprazole i.v. should be discontinued.

To treat long-term disease with increase of acid secretory of the stomach, such as Zollinger-Ellison-Syndrome, the recommended dosage is 2 vials (80mg) per day of Pantoprazol Combino Pharm 40mg. Your doctor could increase or decrease the dose, after tested your stomach acid secretion.

In patients with liver or kidney impairment, or in elderly patients: your doctor will decide the dose that will be administered.

If you have the impression that the effect of Pantoprazol Combino Pharm 40mg is too strong or too weak, talk to your doctor.

If you received more Pantoprazol Combino Pharm 40mg than you should

This medicine is only administered in a hospital by healthcare professionals. It is little probably that you have been given more than you should; However, if you think that you have been given more than you should tell your doctor immediately.

Information for your doctor: In the case of overdosage with clinical signs of intoxication, the usual rules of intoxication therapy apply.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pantoprazol Combino Pharm 40mg can cause side effects, although not everybody gets them.

The assessment of side effects is based on the following frequencies:

Very Common (affects at least 1 in 10 people)

Common (affects at least 1 in 100, but less than 1 in 10 people)

Uncommon (affects at least 1 in 1000, but less than 1 in 100 people)

Rare (affects at least 1 in 10.000, but less than 1 in 1000 people)

Very rare (affects less than 1 in 10.000, included isolated cases)

Blood and lymphatic system disorders:

Very rare: decrease of white blood cells (leukopenia) and/or blood platelets (thrombocytopenia).

Gastrointestinal disorders:

Common: upper abdominal pain, diarrhoea, constipation, flatulence.

Uncommon: nausea and/or vomiting.

Rare: dry mouth

General disorders:

Very rare: fever and liquids retention (peripheral oedema). To go down when finished the treatment.

Hepatobiliary disorders:

Very rare: increased enzymes of the liver (transaminases, GT), severe liver damage showed by jaundice (yellow color on the skin) with or without liver failure.

Immune system disorders:

Very rare: anaphylactic reactions including anaphylactic shock.

Metabolism disorders:

Very rare: increased serum lipids.

Musculoskeletal, connective tissue disorders:

Rare: Pain in joint.

Very rare: muscular pain that disappear when finished the treatment.

Nervous system disorders:

Common: headache.

Uncommon: dizziness, visual disturbances (blurred vision).

Psychiatric disorders:

Very rare: depression that disappear when finished the treatment.

Renal and urinary disorders:

Very rare: interstitial nephritis.

Skin and subcutaneous tissue disorders:

Uncommon: anaphylactic reaction such as itching and skin redness.

Very rare: skin injury (urticaria) and swelling face (angioedema), and severe reactions of the skin with erythema multiforme, Stevens-Johnson syndrome, Lyell syndrome and photosensitivity.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Pantoprazol Combino Pharm 40mg Powder for Solution for injection

Keep out of the reach and sight of children.

Do not store above 30°C. Keep the container in the original package.

Do not use Pantoprazol Combino Pharm 40mg after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Pantoprazol Combino Pharm 40mg contains

- The active substance is Pantoprazole. Each vial contains 40mg of pantoprazol (as pantoprazole sodium sesquihydrate).
- The other ingredients are none.

What Pantoprazol Combino Pharm 40mg looks like and contents of the pack

Powder for Solution for Infusion

White powder.

Pantoprazol Powder is supplied in packs of 1 vial and enclosed in a carton with a package leaflet.

Marketing Authorisation Holder

Combino Pharm SL
Fructuós Gelabert, 6-8
08970 Sant Joan Despí
Spain.

Manufacturer

Hikma Italia SpA
Viale Certosa 10
27100 Pavia
Italy

This leaflet was last approved in {MM/YYYY}

This information is intended for medical or healthcare professionals only:

A ready-to-use solution is prepared by injecting 10ml of physiological sodium chloride solution into the vial containing the dry substance. This solution may be administered directly or may be administered after mixing with 100ml physiological sodium chloride solution, or 5% glucose.

After preparation the solution must be used within 12 hours, although from a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 12 hours at not more than 25°C.

Pantoprazol Combino Pharm 40mg should not be manufactured or mixed with solvents other than those stated. The medicinal product should be administered intravenously over 2-15 minutes.

Any product that has remained in the container or the visual appearance of which has changed (e.g. if cloudiness or precipitation is observed) has to be discarded.

The contents of the vial is for single use only.