

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Pantoprazole Teva 40 mg Powder for Solution for Injection or Infusion** Pantoprazole

#### **Read all of this leaflet carefully before you start using this medicine**

- 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 symptoms are the same as yours.
- 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.

#### **In this leaflet:**

1. What Pantoprazole Teva is and what it is used for
2. Before you use Pantoprazole Teva
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## **1 WHAT PANTOPRAZOLE TEVA IS AND WHAT IT IS USED FOR**

Pantoprazole Teva is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

This preparation is injected into a vein and will only be given to you if your doctor thinks pantoprazole injections are more suitable for you at the moment than pantoprazole tablets. Tablets will replace your injections as soon as your doctor sees fit.

#### **Pantoprazole Teva is used for treating:**

- Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.
- Stomach and duodenal ulcers.
- Zollinger-Ellison-Syndrome and other conditions producing too much acid in the stomach.

## **2 BEFORE YOU USE PANTOPRAZOLE TEVA**

#### **Do not use Pantoprazole Teva:**

- if you are allergic (hypersensitive) to pantoprazole sodium or any of the other ingredients of Pantoprazole Teva (see section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

#### **Take special care with Pantoprazole Teva:**

- If you have severe liver problems. Please tell your doctor if you ever had problems with your liver in the past. He will check your liver enzymes more frequently. In the case of a rise of liver enzymes the treatment should be stopped.

- If you are taking a medicine containing atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- Taking a proton pump inhibitor like pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

**Tell your doctor immediately** if you notice any of the following symptoms:

- an unintentional loss of weight
- repeated vomiting
- difficulty in swallowing
- vomiting blood
- you look pale and feel weak (anaemia)
- you notice blood in your stools
- severe and/or persistent diarrhoea, as pantoprazole has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

### **Taking other medicines**

Pantoprazole injections may influence the effectiveness of other medicines, so tell your doctor if you are taking

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because pantoprazole may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Atazanavir (used to treat HIV-infection).

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

### **Pregnancy and breast-feeding**

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. If you are pregnant, or think you may be pregnant, or if you are breast-feeding, you should use this medicine only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

### **Important information about some of the ingredients of Pantoprazole Teva**

This medicine contains less than 1 mmol **sodium** (23 mg) per vial, i.e. is essentially 'sodium-free'.

## **3 HOW TO USE PANTOPRAZOLE TEVA**

Your nurse or your doctor will administer the daily dose to you as an injection into a vein over a period of 2 - 15 minutes.

The usual dose is:

**For gastric ulcers, duodenal ulcers and reflux oesophagitis.**

One vial (40 mg pantoprazole) a day.

**For the long-term treatment of Zollinger-Ellison syndrome and other conditions in which too much stomach acid is produced.**

Two vials (80 mg pantoprazole) a day.

Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If you are prescribed more than two vials (80 mg) a day, the injections will be given in two equal doses. Your doctor may prescribe a temporary dose of more than four vials (160 mg) a day. If your stomach acid level needs to be controlled rapidly, a starting dose of 160 mg (four vials) should be enough to lower the amount of stomach acid sufficiently.

#### **Special patient groups:**

- If you suffer from severe liver problems, the daily injection should be only 20 mg (half a vial).
- Children (under 18 years). These injections are not recommended for use in children.

#### **If you use more Pantoprazole Teva than you should**

These doses are carefully checked by your nurse or your doctor so an overdose is extremely unlikely. There are no known symptoms of overdose.

If you have any further questions regarding the use of your medicine, ask your doctor or a pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines Pantoprazole Teva can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

not known (frequency cannot be estimated from the available data)

If you get any of the following side effects, tell your doctor immediately or contact the casualty department at your nearest hospital:

• **Serious allergic reactions (frequency rare):** swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.

• **Serious skin conditions (frequency not known):** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme) and sensitivity to light.

• **Other serious conditions (frequency not known):** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys).

Other side effects are:

- **Common** (affects 1 to 10 users in 100)

inflammation of the wall of the vein and blood clotting (thrombophlebitis) where the medicine is injected.

- **Uncommon** (affects 1 to 10 users in 1,000)

headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders; fracture of hip, wrist or spine.

- **Rare** (affects 1 to 10 users in 10,000)

disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males.

- **Very Rare** (affects less than 1 user in 10,000)

disorientation.

- **Not known** (frequency cannot be estimated from the available data)

Hallucination, confusion (especially in patients with a history of these symptoms); decreased sodium level in blood.

If you are on pantoprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

#### **Side effects identified through blood tests:**

- **Uncommon** (affects 1 to 10 users in 1,000)

an increase in liver enzymes.

- **Rare** (affect 1 to 10 users in 10,000)

an increase in bilirubin; increased fats in the blood.

- **Very Rare** (affects less than 1 user in 10,000)

a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections.

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 PANTOPRAZOLE TEVA**

### **Keep out of the reach and sight of children.**

Do not take your medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the vial in the outer carton in order to protect from light

Chemical and physical in-use stability has been demonstrated for 6 hours at 25°C and for 24 hours at 2-8°C. From a microbiological point of view, the reconstituted / diluted solution 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 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

The reconstituted solution should be inspected visually prior to use. It should only be used if the solution is clear and practically free from particles.

Do not use Pantoprazole Teva if you notice that the visual appearance has changed (e.g. if cloudiness or precipitation is observed).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Pantoprazole Teva contains:

The active ingredient is pantoprazole. Each vial contains 40 mg pantoprazole (as pantoprazole sodium),

The other ingredient is disodium edetate.

### What Pantoprazole Teva looks like and contents of the pack

Pantoprazole Teva is a white to almost white dry powder in a clear glass vial with a rubber stopper and sealed with aluminium caps fitted with plastic flip-off discs. Each package contains 1 injection bottle.

Pantoprazole Teva 40 mg Powder for Solution for Injection or Infusion is available in packs of 1, 5 and 10 vials:

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### *Marketing Authorisation Holder*

Teva Pharma B.V.  
Computerweg 10  
3542DR Utrecht  
The Netherlands

#### *Manufacturer*

TEVA Pharmaceutical Works Private Limited Company  
H-2100 Gödöllő, Táncsics Mihály út 82  
Hungary

Merckle GmbH,  
Ludwig-Merckle-Straße 3  
89143 Blaubeuren,  
Germany

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium	Pantoprazole Teva 40 mg poeder voor oplossing voor injectie of infusie
Bulgaria	PRAZOLPAN 40mg powder for solution for injection
Cyprus	Pantoprazole 40mg Teva
Denmark	Pantojekt
Finland	Pantoprazole Teva 40mg injektio/infuusiokuiva-aine, liuosta varten
France	PANTOPRAZOLE TEVA 40mg/ml, poudre pour solution injectable ou pour perfusion
Germany	Pantoprazol Ratiopharm 40 mg Injektionslösung

Greece	Pantoprazole Sodium Teva 40 mg Κόνις για ενέσιμο διάλυμα ή διάλυμα προς έγχυση
Hungary	Pantoprazol-Teva 40mg por oldatos injekcióhoz vagy infúzióhoz
Ireland	Pantoprazole Teva 40 mg Powder for Solution for Injection or Infusion
Luxembourg	Pantoprazol-ratiopharm 40 mg Injektionslösung
Norway	Pantoprazole Teva 40 mg Pulver til injeksjonsvæ oppløsning
Romania	Pantoprazol Teva 40 mg pulbere pentru soluție injectabilă sau perfuzabilă
Spain	Pantoprazol Teva 40mg Polvo para solucion inyectable o perfusion EFG
Slovenia	Pantoprazol Teva 40 mg prašek za raztopino za injiciranje ali infundiranje
Sweden	Pantoprazole Teva 40mg pulver till injections-/infusionsvätska, lösning
The Netherlands	Pantoprazol 40 mg PCH PVI, poeder voor oplossing voor injectie of infusie
United Kingdom	Pantoprazole 40 mg Powder for Solution for Injection or Infusion

**This leaflet has last been revised in 08/2013.**

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**The following information is intended for medical or healthcare professionals only:**

A ready-to-use solution is prepared by injecting 10 ml of sodium chloride 9 mg/ml (0.9%) solution for injection into the vial containing the dry powder. This solution may either be administered directly or after mixing it with 100 ml sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 55 mg/ml (5%) solution for injection.

The reconstituted solution should be inspected visually prior to use. It should only be used if the solution is clear and practically free from particles.

Pantoprazole Teva should not be prepared or mixed with solvents other than those stated.

After preparation, the solution must be used within 6 hours if it is stored at 25°C or within 24 hours at 2-8°C. 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 24 hours at 2 to 8°C.

The medicine should be administered intravenously over 2 - 15 minutes.

The content of the vial is for single intravenous use only. Any product that has remained in the container or whose visual appearance has changed (e.g. if cloudiness or precipitation is observed) must be discarded.