

# Panto TAD<sup>®</sup> 20 mg gastro-resistant tablets

Active substance: Pantoprazole



**Read all of this leaflet carefully before you start taking 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.

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2. Before you take Panto TAD 20 mg
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## 1. WHAT PANTO TAD 20 MG IS AND WHAT IT IS USED FOR

Panto TAD 20 mg belongs to a group of medicines called proton pump inhibitors. Proton pump inhibitors reduce the amount of acid that your stomach makes.

You have been given Panto TAD 20 mg tablets because you have a condition caused by stomach acid.

**Panto TAD 20 mg gastro-resistant tablets are used:**

- in the treatment of mild gastroesophageal reflux disease (a condition in which gastric content may rise up to the esophagus and which can be associated with esophagitis) caused by acid secretion, and the associated symptoms, such as heartburn, acidic belches and pains on swallowing
- in the long-term treatment and in the prevention of relapse in reflux esophagitis (a condition in which backwash of gastric content in esophagus lead to inflammation and pain)
- in the prevention of gastric and duodenal ulcers caused by anti-inflammatory drugs in high-risk patients needing continuous treatment with anti-inflammatory drugs.

## 2. BEFORE YOU TAKE PANTO TAD 20 MG

**Do not take Panto TAD 20 mg**

- if you are allergic (hypersensitive) to pantoprazole or any of the other ingredients of Panto TAD 20 mg
- if you are taking atazanavir (which is used for the treatment of HIV infection).

**Take special care with Panto TAD 20 mg**

- Please tell the doctor who prescribed this medicine:
- if you have severe liver impairment. In case of severe hepatic disorder your doctor should monitor your liver function while you use Panto TAD 20 mg
  - if you have been diagnosed with vitamin B12 malabsorption
  - if your doctor has given you Panto TAD 20 mg together with anti-inflammatory medicines to treat your pain or rheumatic disease; please also read the package leaflets of these medicines carefully
  - if you take Panto TAD 20 mg on a long-term basis (longer than 1 year): Your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Please tell your doctor if you suffer or have recently suffered from any of the following symptoms: unintentional weight loss, recurrent vomiting or vomiting of blood, or dark stool. Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease.

Panto TAD 20 mg tablets are not recommended for children.

**Taking other medicines**

Other concomitant medication may affect the efficacy and safety of this medicine. Panto TAD 20 mg may also affect the efficacy and safety of other medicines.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Panto TAD 20 mg can cause side effects, although not everybody gets them.

The frequencies are defined as

<b>common</b>	less than 1 in 10, but more than 1 in 100 people
<b>uncommon</b>	less than 1 in 100, but more than 1 in 1000 people
<b>rare</b>	less than 1 in 1000, but more than 1 in 10,000 people
<b>very rare</b>	less than 1 in 10,000 people including isolated cases

*Common:*

Upper abdominal pain, diarrhoea, constipation, flatulence and headache.

*Uncommon:*

Nausea, vomiting, dizziness, blurred vision and allergic reactions such as itching and rash.

*Rare:*

Dry mouth, joint pain.

*Very rare:*

White blood cell deficiency (leucopenia), platelet deficiency (thrombocytopenia), swelling of hands and feet, severe liver cell damage and associated jaundice with potential liver failure, severe allergic reaction manifested as acute general symptoms with potential acute and substantial drop in blood pressure, elevated liver enzyme and triglyceride levels, elevated body temperature, muscle pain, depression, kidney inflammation, hives, hypersensitivity/attacks of local skin and mucous membrane swelling in the face, limbs, lips, tongue, larynx and/or vocal cords (angioedema, see special warning below), photosensitivity reactions and severe skin reactions such as Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis (Lyell's syndrome).

**You should stop taking Panto TAD 20 mg and see your doctor immediately if you experience symptoms of angioedema, such as**

- **swollen face, tongue or throat**
- **difficulty to swallow**
- **hives and difficulties to breathe**

*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 PANTO TAD 20 MG

Keep out of the reach and sight of children.  
Blister pack: Store in the original package in order to protect from moisture.  
HDPE container: Keep the HDPE container tightly closed in order to protect from moisture.

Do not use Panto TAD 20 mg after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

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 Panto TAD 20 mg contains**

- Each gastro-resistant tablet contains 20 mg pantoprazole (as pantoprazole

...Panto TAD 20 mg may also affect the efficacy and safety of other medications. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Remember to tell your doctor about your treatment with Panto TAD 20 mg if you are prescribed another medicine while the treatment is still ongoing. It is especially important to tell your doctor:

- if you are using atazanavir which is used for the treatment of HIV infection
- if you are using ketoconazole or itraconazole which are used for the treatment of fungal infections, since pantoprazole may affect their concentrations in your body
- if you are using anticoagulant medicines, e.g. warfarin, since it may be necessary to monitor your blood coagulation tests more often.

**Taking Panto TAD 20 mg with food and drink**  
Take Panto TAD 20 mg tablets with water before a meal.

**Pregnancy and breast-feeding**  
Ask your doctor or pharmacist for advice before taking any medicine.

Experience with use of Panto TAD 20 mg in pregnant women is limited. There is no information on the excretion of pantoprazole into human breast milk. If you are pregnant or if you are breast-feeding, you should use this medicine only if your treating physician considers the benefit for you greater than the potential risk for your unborn child or baby.

**Driving and using machines**  
There are no known effects on the ability to drive and use machines. Adverse drug reactions such as dizziness and visual disturbances may occur and which may decrease the ability to react.

**Important information about some of the ingredients of Panto TAD 20 mg**

Intolerance to sugars: This medicine contains sorbitol. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. HOW TO TAKE PANTO TAD 20 MG

Always take Panto TAD 20 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Method of administration**  
Do not chew or crush Panto TAD 20 mg tablets but swallow them whole with liquid before a meal.

**Dosage**  
Always take Panto TAD 20 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about the dosage.

**Treatment of mild reflux disease and the associated symptoms (e.g. heartburn, acidic belches and pain in swallowing):**  
The recommended dose is 1 tablet (20 mg) daily.

**Long-term treatment and the prevention of relapse in reflux esophagitis:**  
For long term treatment the recommended dose is 1 tablet (20 mg) daily, if relapse occurs, the dosage is increased to 40 mg daily (2 x 20 mg tablets or 1 x 40 mg tablet).

**Prevention of gastric and duodenal ulcers caused by anti-inflammatory drugs:**  
The recommended dose is 1 tablet (20 mg) daily.

**Elderly and patients with renal impairment:**  
Daily dose of 40 mg should not be exceeded.

**Patients with hepatic impairment:**  
Daily dose of 20 mg should not be exceeded.

**Children:**  
Panto TAD 20 mg gastro-resistant tablets should not be used in children.

**If you take more Panto TAD 20 mg than you should**  
If you or someone you know accidentally takes a lot more than the stated dose (an overdose) you should contact a doctor immediately.

**If you forget to take Panto TAD 20 mg**  
If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Panto TAD 20 mg**  
Do not change the dosage or stop the medication without discussing it with your doctor first.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

sodium 1.5 H<sub>2</sub>O).  
The other ingredients are mannitol (Ph. Eur.), crospovidone (type B), anhydrous sodium carbonate, sorbitol (Ph. Eur.), calcium stearate (Ph. Eur.) in the tablet core and hypromellose, povidone (K25), titanium dioxide (E171), iron(III) hydroxide oxide x H<sub>2</sub>O (E172), propylene glycol, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 %, sodium lauryl sulphate, polysorbate 80, macrogol 6000 and talc in the film-coating.

**What Panto TAD 20 mg looks like and contents of the pack**  
The 20 mg gastro-resistant tablets are light brownish-yellow, oval, slightly bi-convex tablets.

Pack sizes:  
Boxes of 14, 15, 28, 30, 56, 60, 98, 100 gastro-resistant tablets in blister packs.  
HDPE container of 100 and 250 gastro-resistant tablets.

#### Marketing Authorisation Holder

TAD Pharma GmbH  
Heinz-Lohmann-Straße 5  
27472 Cuxhaven  
Germany  
Telephone: +49 47 21 606-0  
Telefax: +49 47 21 606-333  
E-mail: info@tad.de  
Internet: www.tad.de

#### Manufacturers

TAD Pharma GmbH  
Heinz-Lohmann-Straße 5  
27472 Cuxhaven  
Germany

or  
KRKA, d.d., Novo mesto  
Šmārješka cesta 6  
8501 Novo mesto  
Slovenia

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

Austria	PANTOPRAZOL TEVA 20 mg – magensaftresistente Tabletten
Belgium	PANTOPRAZOLE TEVA 20 mg maagsapresidente tabletten
Denmark	PANTOPRAZOL KRKA 20 mg enterotablet
Finland	PANTOPRAZOLE KRKA 20 mg enterotabletti
France	PANTOPRAZOLE TEVA 20 mg comprimé gastro-résistant
Germany	PANTOPRAZOL TAD 20 mg magensaftresistente Tabletten
Greece	PANTOPRAZOLE KRKA 20 mg γαστροανθεκτικά δισκία
Ireland	PANTOPRAZOLE KRKA 20 mg gastro-resistant tablets
Italy	PANTOPRAZOLE TEVA 20 mg compresse gastroresistenti
United Kingdom	PANTOPRAZOLE 20 mg gastro-resistant tablets
Netherlands	PANTOPRAZOL 20 mg msr PCH, maagsapresidente tabletten
Norway	PANTOPRAZOL KRKA 20 mg enterotablet
Sweden	PANTOPRAZOL KRKA 20 mg enterotablet
Spain	PANTOPRAZOL TEVA 20 mg comprimidos gastroresistentes EFG
Malta	PANTOPRAZOLE KRKA 20 mg pilloli gastro-rezistenti
Portugal	PANTOPRAZOLE KRKA 20 mg Comprimido gastroresistente
Poland	NOLPAZA 20 mg tabletki dojelitowe
Slovak Republic	NOLPAZA 20 mg gastrorezistentne tablety
Latvia	NOLPAZA 20 mg tableti šķīstošās
Estonia	NOLPAZA
Lithuania	NOLPAZA 20 mg skrandyje neirios tabletes
Czech Republic	NOLPAZA 20 mg enterosolventni tablety

This leaflet was last updated in October 2011.