

Package leaflet Information for the user

Panto AIWA 20 mg gastro-resistant tablets

Pantoprazole

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- If you need any more information or advice, ask your doctor or pharmacist.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.
- You should not take Panto AIWA 20 mg for more than 4 weeks without consulting a doctor.

What is in this leaflet

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2. What you need to know before you take Panto AIWA 20 mg
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1. WHAT PANTO AIWA 20 MG IS AND WHAT IT IS USED FOR

Panto AIWA 20 mg contains the active substance pantoprazole, which blocks the 'pump' that produces stomach acid. Hence it reduces the amount of acid in your stomach.

Panto AIWA 20 mg is used for the short-term treatment of reflux symptoms (for example heartburn, acid regurgitation) in adults. Reflux is the backflow of acid from the stomach into the gullet ("food pipe"), which may become inflamed and painful. This may cause symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with Panto AIWA 20 mg, but this medicine is not meant to bring immediate relief. It may be necessary to take the tablets for 2-3 consecutive days to relieve the symptoms.

You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PANTO AIWA 20 MG

Do not take Panto AIWA 20 mg

- if you are allergic to pantoprazole or any of the other ingredients of this medicine (listed in section 6).
- if you are taking a medicine containing atazanavir (for the treatment of an HIV-infection). See "Other medicines and Panto AIWA 20 mg".

Warnings and precautions

Please talk to your doctor before taking Panto AIWA 20 mg

- if you have been treated for heartburn or indigestion continuously for 4 or more weeks.
- if you are over 55 years old and taking non-prescription medicines for indigestion on a daily basis.
- if you are over 55 years old and have any new or recently changed reflux symptoms.
- if you have had a gastric ulcer or stomach surgery.

- if you have liver problems or jaundice (yellowing of skin or eyes).
- if you regularly see your doctor for serious complaints or conditions.
- if you are due to have an endoscopy or a breath test called ¹³C urea breath test.

Tell your doctor immediately, before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:

- unintentional weight loss (not related to a diet or an exercise programme)
- vomiting, particularly if repeated
- vomiting blood; this may appear as dark coffee grounds in your vomit
- blood in your stool; which may be black or tarry in appearance
- difficulty in swallowing or pain when swallowing
- you look pale and feel weak (anaemia)
- chest pain
- stomach pain
- severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests.

Please consult your doctor before you take this drug if

- you are about to undergo a creatin blood test (Chromogranin A)

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with Panto AIWA 20 mg, but this medicine is not meant to bring immediate relief. You should not take it as a preventive measure.

If you have been suffering from recurrent heartburn or indigestion for a longer period of time, remember to see your doctor regularly.

Children and teenagers

Panto AIWA 20 mg should not be used by children and teenagers under 18 years of age due to a lack of safety information for this age group.

Other medicines and Panto AIWA 20 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Panto AIWA 20 mg may influence the effectiveness of other medicines. This especially applies to medicines containing one of the following active substances:

- atazanavir (used to treat HIV-infections). You must not take pantoprazole if you are taking atazanavir. See "Do not take Panto AIWA 20 mg".
- ketoconazole (used for fungal infections).
- warfarin or phenprocoumon (used to thin blood and prevent clots). Further blood tests may be required.
- methotrexate (used to treat rheumatoid arthritis, psoriasis and cancer) – if you are taking methotrexate, your doctor may temporarily stop your treatment with Panto AIWA 20 mg because pantoprazole can increase levels of methotrexate in the blood.

Do not take Panto AIWA 20 mg with other medicines which reduce the amount of acid produced in your stomach, such as other proton pump inhibitors (omeprazole, lansoprazole or rabeprazole) or an H₂ blocker (e.g. ranitidine, famotidine).

However, you may take Panto AIWA 20 mg with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate or combinations thereof), if needed.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

3. HOW TO TAKE PANTO AIWA 20 MG

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet a day. Do not exceed this recommended daily dose of 20 mg pantoprazole.

You should take this medicine for at least 2-3 consecutive days. Stop taking Panto AIWA 20 mg when you are completely symptom-free. You may experience relief from your acid regurgitation and heartburn symptoms after just one day of treatment with Panto AIWA 20 mg, but this medicine is not meant to bring immediate relief.

If you have no symptom-relief after taking this medicine for 2 weeks continuously, consult your doctor. Do not take Panto AIWA 20 mg for more than 4 weeks without consulting your doctor.

Take the tablet before a meal, at the same time every day. You should swallow the tablet whole with some water. Do not chew or break the tablet.

If you take more Panto AIWA 20 mg than you should

Tell your doctor or pharmacist if you have taken more than the recommended dose. If possible, take the medicine and this leaflet with you.

If you forget to take Panto AIWA 20 mg

Do not take a double dose to make up for a forgotten dose.

Simply take your regular dose when you would normally take your next dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately or contact the emergency department at your nearest hospital if you get any of the following **serious side effects**. Stop taking this medicine straight away and take this leaflet and/or the tablets with you.

Severe hypersensitivity reactions (rare: may affect up to 1 in 1,000 patients):

Hypersensitivity reactions, so-called anaphylactic reactions, anaphylactic shock and angioedema. Typical symptoms are: swelling of the face, lips, mouth, tongue and/or throat, which may cause difficulty in swallowing or breathing; wheals (hives); severe dizziness with very fast heartbeat and heavy sweating.

Severe skin reactions (frequency not known: frequency cannot be estimated from the available data): rash with swelling, blistering or peeling of the skin, losing skin and slight bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash when exposed to the sun.

Other severe reactions (frequency not known): yellowing of the skin and eyes (due to severe liver damage) or kidney problems such as painful urination and lower back pain with fever.

Other possible side effects include:

Frequently observed side effects (up to 1 out of 10 users may be concerned):

Benign gastric polyps

Uncommon side effects (may affect up to 1 in 100 patients)

headache, dizziness, diarrhoea, nausea, vomiting, bloating and flatulence, constipation, dry mouth, pain and discomfort in the upper abdomen, skin rash or hives, itching, feeling weak, exhausted or generally unwell, sleep disorders, increase in liver enzymes in blood tests.

Rare side effects (may affect up to 1 in 1,000 patients)

distortion or complete lack of the sense of taste, disturbances in vision such as blurred vision, pain in the joints, muscle pains, weight changes, raised body temperature, swelling of the extremities, depression, increased bilirubin and fat levels in blood (seen in blood tests), breast enlargement in males, high fever and a sharp drop in circulating granular white blood cells (seen in blood tests).

Very rare side effects (may affect up to 1 in 10,000 patients)

disorientation; reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells as well as platelets (seen in blood tests).

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

hallucinations, confusion (especially in patients with a history of these symptoms), decreased level of sodium in the blood, decreased level of magnesium in the blood.

Inflammation of the colon causing persistent watery

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the *Bundesinstitut für Arzneimittel und Medizinprodukte* [Federal Institute for Drugs and Medical Devices], *Abt. Pharmakovigilanz* [Pharmacovigilance Department], Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PANTO AIWA 20 MG

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and container after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

<For packs to be exported to countries of climatic zone III: Do not store above 25°C.>

Do not throw away medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Panto AIWA 20 mg contains

The active substance is pantoprazole. Each gastro-resistant tablet contains 20 mg pantoprazole (as sodium sesquihydrate 1.5 H₂O).

The other ingredients are:

Tablet core: mannitol (Ph.Eur.), sodium carbonate, carboxymethyl starch sodium (type A), methacrylic acid-ethyl acrylate copolymer, calcium stearate (Ph.Eur.);

Tablet coating: Opadry White OY-D-7233, consisting of: hypromellose, titanium dioxide (E171), talc, macrogol 400, sodium dodecyl sulphate;

Gastro-resistant coating: Kollicoat MAE 30 DP, yellow, consisting of: methacrylic acid-ethyl acrylate copolymer dispersion 30%, propylene glycol, iron(III) oxide-hydroxide x H₂O (E172), titanium dioxide (E171), talc, purified water.

What Panto AIWA 20 mg looks like and contents of the pack

The gastro-resistant tablets are oval, biconvex and pale yellow.
ALU/ALU blister packs with 7 and 14 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

T&D Pharma GmbH
Lemgoer Str. 16
32689 Kalletal

Phone: +49 (0)5264/655 999 20

Fax: +49 (0)5264/655 999 30

info@td-pharma.de

www.td-pharma.de

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Manufacturing site:

Balkanpharma Dupnitsa AD
3, Samokovsko Shosse Str.
Dupnitsa 2600, Bulgaria