

PANTOPRAZOLE WINTHROP® TABLET

Pantoprazole sodium sesquihydrate (20mg)

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What Pantoprazole Winthrop Tablet is used for

Pantoprazole Winthrop Tablet is used for:

- Treatment of mild reflux disease and associated symptoms (e.g. heartburn, acid regurgitation, pain on swallowing)
- Long-term treatment and prevention of relapse in reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitation of stomach acid)
- Prevention of stomach and duodenal ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs), in people at risk who need to take NSAIDs continuously.

How Pantoprazole Winthrop works

Pantoprazole 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.

Before you use Pantoprazole Winthrop Tablet

When you must not use it

Do not take Pantoprazole Winthrop Tablet if:

- You are allergic (hypersensitive) to pantoprazole, or any of the other ingredients. (Listed in section ingredients below)
- You are taking a medicine containing atazanavir for treatment of Human Immunodeficiency Virus infection (HIV)

Before you start to use it

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

Taking other medicines

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

- Ketoconazole or itraconazole (used to treat fungal infections)
- Atazanavir (used to treat HIV-infection)
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood

How to use Pantoprazole Winthrop Tablet

Always take Pantoprazole Winthrop Tablet exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The tablets must not be chewed or crushed. Swallow the tablet whole with some water.

How much to use

Adults and adolescents 12 years of age and above:

Treatment of mild reflux disease and associated symptoms

The usual dose is one pantoprazole 20mg tablet a day. This dose usually brings relief within 2 – 4 weeks. If not sufficient, healing will normally be achieved within another 4 weeks of treatment. After this, any recurring symptoms can be controlled by taking one pantoprazole 20mg tablet daily, when required.

Long-term treatment and prevention of relapse in reflux oesophagitis

The usual dose is one pantoprazole 20mg tablet a day. The dose can be increased to 40mg a day in the event of a relapse. You can use Pantoprazole Winthrop 40mg Tablet for this. After healing, the dose can be reduced back to one tablet of pantoprazole 20mg a day.

Adults:

Prevention of duodenal and stomach ulcers in people who need to take NSAIDs continuously

The usual dose is one pantoprazole 20mg tablet a day.

Special groups:

- If you suffer from severe liver problems, you should not take more than one tablet a day
- Pantoprazole Winthrop 20mg Tablet is not recommended for use in children below 12 years

When to use it

Take the medicine as instructed by your doctor.

How long to use it

Take the medicine for the duration as instructed by your doctor.

If you forget to use it

Do not take a double dose to make up for a forgotten dose. Take your next dose at the usual time.

If you use too much (overdose)

If you accidentally take too many tablets, contact your doctor.

While you are using it

Things you must do

Always take Pantoprazole Winthrop Tablet exactly as your doctor has told you.

Things you must not do

Do not stop taking the tablets without first talking to your doctor or pharmacist.

Things to be careful of

Take special care with Pantoprazole Winthrop Tablet if:

- You have severe liver problems. Tell your doctor if you have ever had problems with your liver. Your liver enzymes will be checked more frequently, especially when you are taking Pantoprazole Winthrop Tablet as a long-term treatment. If the liver enzyme levels increase, treatment should be stopped.

- You have reduced body stores or risk factors for vitamin B12 malabsorption and receive pantoprazole as a long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.

- Inform your doctor if you need to take NSAIDs continuously.

By taking NSAIDs continuously, you might have an increased risk of developing stomach and intestinal complication. Your doctor may prescribe pantoprazole for you to prevent these complications. Any increased risk will be assessed according to your own personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or of stomach or intestinal bleeding.

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

- Significant unintentional weight loss
- Repeated vomiting
- Difficulty in swallowing
- Vomiting blood
- Anaemia
- Blood in your stools
- Severe and/or persistent diarrhea, as pantoprazole has been associated with a small increase in infectious diarrhea.

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.

If you take Pantoprazole Winthrop Tablet on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance.

Pregnancy and breast-feeding

There are no adequate data for the use of pantoprazole in pregnant women.

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 to be greater than the potential risk for your unborn child. 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 machinery.

Side Effect

Like all medicines, Pantoprazole Winthrop Tablet can cause side effects, although not everyone gets them.

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

Common: $\geq 1/100$ to $< 1/10$

Uncommon: $\geq 1/1,000$ to $< 1/100$

Rare: $\geq 1/10,000$ to $< 1/1,000$

Very rare: $< 1/10,000$, not known (cannot be estimated from available data)

Blood and the lymphatic system disorders

Very rare: reduction in the number of white blood cells, reduction in the number of blood platelets

Immune system disorders

Very rare: anaphylactic reactions (very severe allergic reaction which can be life-threatening) including anaphylactic shock

Psychiatric disorders

Rare: depression, hallucination, disorientation and confusion

Nervous system disorders

Common: headache

Uncommon: dizziness, visual disturbance

Gastrointestinal disorders

Common: upper abdominal discomfort, diarrhoea, constipation, flatulence (wind)

Uncommon: nausea, vomiting

Rare: dry mouth

Liver disorders

Very rare: severe damage to the liver cells leading to jaundice with or without liver failure

Skin disorders

Uncommon: allergic reactions such as itchiness and skin rash

Very rare: hives, rapid swelling of the skin, tissues and mucous membranes (angioedema), severe skin reactions such as Stevens Johnson syndrome, erythema multiforme, Lyell's Syndrome, and sensitivity to light

Musculoskeletal and connective tissue disorders

Rare: joint pain

Very rare: muscle ache

Renal and urinary disorders

Very rare: kidney disorder in which the spaces between the kidney tubules become inflamed (interstitial nephritis)

Reproductive system and breast disorders

Very rare: breast enlargement in males

General disorders

Very rare: swelling of the extremities (peripheral oedema)

Investigations

Very rare: increased liver enzymes, elevated triglycerides, increased body temperature, decreased sodium level in blood in the elderly

Other side effects not listed above may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

**Storage and Disposal of
Pantoprazole Winthrop Tablet**

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Pantoprazole Winthrop Tablet after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not open the blister pack until you are ready to take the medicine.

Disposal

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.

Product Description

What it looks like

Pantoprazole Winthrop 20mg Tablet:
Yellow, oval tablet.

Ingredients:

- Active ingredient: Pantoprazole sodium sesquihydrate.
- Inactive ingredients: Maltitol, crospovidone, carmellose sodium, sodium carbonate, calcium stearate, Opadry II Yellow, triethyl citrate, methacrylic acid – ethyl acrylate copolymer.

MAL Number:

Pantoprazole Winthrop 20mg Tablets
MAL10033152A

Manufacturer

Sanofi-aventis S.p. z.o.o.
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Product Registration Holder

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