

PANTOPRAZOLE WINTHROP[®] TABLET

Pantoprazole sodium sesquihydrate (40mg)

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What Pantoprazole Winthrop Tablet is used for

Pantoprazole Winthrop Tablet is used for treatment of:

- An infection with a bacterium called *Helicobacter pylori* in people with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy). The aim is to get rid of the bacteria and so reduce the likelihood of these ulcers returning
- Stomach and duodenal ulcers
- Moderate or severe reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitating of stomach acid)
- Zollinger-Ellison syndrome and other conditions producing too much acid in the stomach as long term treatment

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)
- You have rare hereditary problems of fructose intolerance

Do not use pantoprazole in combination therapy for the eradication of *Helicobacter pylori* in people with severe liver dysfunction.

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 reflux oesophagitis

The usual dose is one pantoprazole 40mg tablet a day. Sometimes, your doctor may tell you to increase to 2 tablets daily. The treatment period is usually between 4 and 8 weeks.

Adults:

Treatment of infection with *Helicobacter pylori* in people with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy)

One pantoprazole 40mg tablet, two times a day plus two antibiotics of either amoxicillin, clarithromycin and metronidazole, each to be taken two times a day with your pantoprazole tablet. The usual treatment period is 1-2 week.

For *Helicobacter pylori* eradication therapy, the second pantoprazole 40mg tablet should be taken before your evening meal.

The following combinations are recommended:

- a) One pantoprazole 40mg tablet twice daily + 1000mg amoxicillin twice daily + 500mg clarithromycin twice daily
- b) One pantoprazole 40mg tablet twice daily + 400mg to 500mg metronidazole twice daily + 250mg to 500mg clarithromycin twice daily
- c) One pantoprazole 40mg tablet twice daily + 1000mg amoxicillin twice daily + 400mg to 500mg metronidazole twice daily

Treatment of stomach and duodenal ulcers

The usual dose is one pantoprazole 40mg tablet a day. In certain cases, the dose may be doubled. The treatment period for stomach ulcers is usually between 4-8 weeks. The treatment period for duodenal ulcers is usually 2-4 weeks.

Long-term treatment of Zollinger-Ellison syndrome and other conditions in which too much stomach acid is produced

The recommended starting dose is usually two pantoprazole 40mg tablets a day. The treatment period is usually between 4 and 8 weeks.

Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If prescribed more than two tablets a day, take the tablets twice daily.

Special groups

- If you suffer from severe liver problems, the dose should be lowered to one pantoprazole 40mg tablet every other day
- In elderly, a daily dose of pantoprazole 40mg should not be exceed (except in *Helicobacter pylori* eradication therapy)
- Pantoprazole Winthrop 40mg 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 if:

- You are on long-term treatment with pantoprazole for Zollinger-Ellison syndrome and other conditions in which too much stomach acid is produced. Pantoprazole may lead to a reduced absorption of vitamin B12.
- 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 as long-term treatment. If the liver enzyme levels increase, treatment should be stopped.

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 beyond 4 weeks in spite of your treatment, further investigations will be considered.

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(very severe allergic reaction which can be life-threatening) reactions 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 40mg 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 40mg Tablet: Yellow, oval tablet.

Ingredients:

- Active ingredients: 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 40mg Tablet: **MAL10033153A**

Manufacturer

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

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