

PANZOLE TABLET

Pantoprazole sodium sesquihydrate (20mg,40mg)

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What Panzole Tablet is used for

Panzole is used for treating acid-related diseases of the stomach and duodenum.

Pantoprazole 20mg is used:

- to treat symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated with mild reflux disease caused by reflux of acid from the stomach.
- for the long-term management and prevention of reflux oesophagitis from coming back. This can be caused by washing back (reflux) of food and acid from the stomach into the food pipe, also known as the oesophagus.
- for the prevention of stomach and duodenal ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs), in people at risk who need to take NSAIDs continuously.

Pantoprazole 40mg is used:

- in combination with two appropriate antibiotics for the eradication of *Helicobacter pylori* (bacteria) in people with duodenal ulcers and stomach ulcers with the aim to reduce the likelihood of these ulcers returning.
- for duodenal ulcer
- for gastric (stomach) ulcer
- for moderate and severe reflux oesophagitis

Pantoprazole tablet 40mg is not indicated for mild gastro-intestinal complaints such as nervous dyspepsia (indigestion

associated with tension or anxiety).

How Panzole Tablet works

Panzole tablets is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach.

Before you use Panzole Tablet

When you must not take it

Do not take Panzole:

- if you are allergic (hypersensitive) to pantoprazole or any of the other ingredients of Panzole tablets.
- if you are allergic to medicines containing other proton pump inhibitors.

Panzole tablet 40 mg must not be used as combination treatment for the eradication of H.pylori if you have moderate to severe liver or kidney function disturbances.

Before you start to take it

Take special care with Panzole

- If you have severe liver problems. Please tell your doctor if you have ever had problems with your liver. Doctor will check your liver enzymes more frequently, especially when you are taking Panzole tablets as a long-term treatment. If the liver enzyme levels increase, then treatment should be stopped.
- If you need to take medicines called NSAIDs continuously with prescribed Panzole tablets because you have an increased risk of developing stomach and intestinal complications.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole as a long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking a medicine containing atazanavir (for the treatment of human immunodeficiency virus (HIV)-infection) at the same time as pantoprazole, ask your doctor for specific advice.

Pregnancy and breast-feeding

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

There is also no information on the excretion of pantoprazole into human breast milk. 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

You should not drive or operate machinery until you know how the medicine affects you.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, and herbal medicines. This is because Panzole can affect the way some other medicines work. Also, other medicines can affect the way Panzole works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Panzole:

- atazanavir (antiretroviral medicine for treating HIV)
- coumarin (anticoagulants – prevent blood clot)
- ketoconazole (an antifungal – to treat fungal infection).

How to take Panzole Tablet

How much to take

Adults

To treat symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to mild reflux disease

The usual dose is one Panzole Tablet 20mg a day. Your doctor will tell you how long to continue taking the medicine.

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For long-term management and for preventing the return of reflux oesophagitis

The usual dose is one Panzole Tablet 20mg a day. If the illness returns, your doctor can double the dose, in which case you can take one Panzole Tablet 40mg a day. After healing, you can reduce the dose back again to one Panzole Tablet 20mg a day.

To prevent duodenal and stomach ulcers in patients who need to take NSAIDs continuously

The usual dose is one Panzole Tablet 20mg a day.

For treatment of *Helicobacter pylori* positive

Eradication of the germ by a combination therapy should be given:

- a) twice daily one tablet Panzole tablet 40mg + twice daily 1000 mg amoxicillin + twice daily 500 mg clarithromycin
- b) twice daily one tablet Panzole tablet 40mg + twice daily 500 mg metronidazole + twice daily 500 mg clarithromycin
- c) twice daily one tablet Panzole tablet 40mg + twice daily 1000 mg amoxicillin + twice daily 500 mg metronidazole

Children

These tablets are not recommended for use in children.

Special patient groups:

- If you suffer from severe liver problems, you should not take more than one Panzole Tablet 20mg a day.

When to take it

Take the tablets 1 hour before a meal, without chewing or crushing them, and swallow them whole with some water.

How long to take it

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

For *H.pylori* cases, the combination therapy is implemented for 7 days in

general and can be prolonged to up to two weeks maximum.

A duodenal ulcer generally heals within 2 weeks. If a 2-week period of treatment is not sufficient, healing will be achieved in almost all cases within a further 2 weeks.

A 4-week period is usually required for the treatment of gastric ulcers and reflux esophagitis. If this is not sufficient, healing will usually be achieved within a further 4 weeks.

If you forget to take it

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

If you take too much (overdose)

Tell your doctor or pharmacist. There are no known symptoms of overdose.

While you are using Panzole Tablet

Things you must do

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

Things you must not do

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

Things to be careful of

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

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 Panzole tablets 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.

Side Effects

Like all medicines, Panzole tablets can cause side effects, although not everybody gets them.

The most common side effects includes:

- diarrhoea
- upper abdominal pain
- constipation, flatulence
- headache

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 Panzole Tablet

Storage

Store below temperature 30°C.

Disposal

Do not consume the medicine after the expiry date stated on the label.

Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

Product Description

What it looks like

Panzole Tablet 20mg are yellow coloured, oval, 8.7 mm in length, plain on both sides, biconvex enteric-coated tablets.

Panzole Tablet 40mg are yellow coloured, oval, 11.5 mm in length, plain on both sides, biconvex enteric-coated tablets.

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Ingredients

Active ingredient

Panzole Tablet 20mg contains pantoprazole 20mg.

Panzole Tablet 40mg contains pantoprazole 40mg.

Inactive ingredients

Panzole tablets also contain the following excipients: Mannitol, Sodium carbonate anhydrous, Sodium starch glycollate, Crospovidone, Silica-colloidal anhydrous, Calcium stearate, Hypromellose, Macrogol 6000, Purified water, Sodium hydroxide, Eudragit L30 D 55 and Opadry AMB 80 W 52172.

MAL Numbers

Panzole Tablet 20mg:

MAL12040009AC

Panzole Tablet 40mg:

MAL12040008AC

Manufacturer

Ipca Laboratories Ltd
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Product Registration Holder

Actavis Sdn Bhd
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Date of Revision

01-06-2015

Serial Number:

BPFK(R4/1)010615/00133