

Pantoprazole – AFT

Pantoprazole (as sodium sesquihydrate) 40 mg powder for injection

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Pantoprazole-AFT.

This leaflet answers some common questions about Pantoprazole-AFT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Pantoprazole-AFT against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Pantoprazole – AFT is used for

- **Ulcers**

Pantoprazole-AFT is used to treat and help heal duodenal and gastric ulcers.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out of the stomach.

These can be caused in part by too much acid being made in the stomach.

- **Reflux disease**

Pantoprazole-AFT is also used to treat reflux oesophagitis or reflux disease. This can be caused by “washing back” (reflux) of food

and acid from the stomach into the food pipe, also known as the Oesophagus.

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Pantoprazole-AFT is also used to prevent reflux oesophagitis from coming back.

- **Zollinger-Ellison syndrome**

Pantoprazole-AFT is used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces very large amounts of acid, much more than in ulcers and reflux disease.

This medicine belongs to a group of medicines called proton pump inhibitors (PPIs).

This medicine works by decreasing the amount of acid the stomach makes to give relief from the symptoms and allow healing to take place.

Ask your doctor if you have any questions about why it has been prescribed for you. Your doctor may have prescribed it for another purpose.

This medicine is not addictive.

This medicine is available only with a doctor’s prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery. However, do not drive a car or operate machines if you experience side effects such as dizziness or blurred vision.

Before you are given Pantoprazole – AFT

When you must not be given it

You should not be given Pantoprazole – AFT if you have an allergy to:

- pantoprazole
- any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not use Pantoprazole-AFT in combination with atazanavir or nelfinavir (anti-viral medications).

Do not give Pantoprazole-AFT injection to children. Safety and effectiveness in children have not been established.

Do not use it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any other medical conditions.

Tell your doctor if you are pregnant, plan to become pregnant or breast feeding.

Your doctor can discuss with you the risks and benefits involved in using Pantoprazole – AFT.

If you have not told your doctor about any of the above, tell him/her

before you are given pantoprazole - AFT.

Tell your doctor if you have any of the following symptoms:

- unintentional weight loss
- repeated vomiting
- vomiting blood
- difficulty or pain when swallowing
- you look pale or feel weak
- you notice blood in your stools

Your doctor may need to perform some additional tests before you take Pantoprazole-AFT Injection

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket, health food shop, naturopath or herbalist.

Some medicines and Pantoprazole – AFT may interfere with each other.

These include:

- warfarin, phenprocoumon - medicines used to prevent blood clots (anticoagulants)
- ketoconazole, itraconazole, posaconazole - medicines used to treat fungal infection
- atazanavir, nelfinavir – medicines used to treat viral infections such as HIV
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer
- tacrolimus, mycophenolate mofetil - medicines used to suppress the immune system
- fluvoxamine - a medicine used to treat anxiety and depression

These medicines may be affected by Pantoprazole – AFT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

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How to use Pantoprazole – AFT

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to use and when to use it

The dose and frequency of your Pantoprazole-AFT Injection will be determined by your doctor and will depend on your medical condition. Your doctor may change the dose as your condition changes.

How to use it

Pantoprazole Injection is reconstituted with sodium chloride solution by your doctor or pharmacist.

How long to use it

Continue using your medicine for as long as your doctor tells you. Your doctor will determine how long you need to be treated with Pantoprazole-AFT Injection.

If a dose is missed

If a dose of Pantoprazole-AFT Injection is missed, your doctor will determine when your next dose is due.

If you take too much (overdose)

Pantoprazole – AFT is given by a doctor or nurse so an overdose is not likely to occur. Contact your doctor if you are concerned about the dose.

An overdose may cause an increase in side effects. (The side effects are listed under the heading, ‘Side effects’ in this leaflet.).

If you think that you or anyone else may have taken too much, immediately telephone your doctor or the National Poisons Centre

(telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

While you are being given Pantoprazole – AFT

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Pantoprazole-AFT Injection.

Tell any other doctors, dentists and pharmacists who treat you that you are being given Pantoprazole-AFT Injection.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

If you become pregnant while you are being given this medicine, tell your doctor immediately.

Keep all of your doctor’s appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Pantoprazole – AFT affects you.

This medicine may cause dizziness and visual disturbances in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Pantoprazole – AFT.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse as soon as possible if you notice any of the following and they worry you:

- headache
- diarrhoea
- nausea or vomiting
- stomach pain
- excessive gas in the stomach bowel
- indigestion
- constipation
- increased sweating or body temperature
- dry mouth
- pain and swelling at the site of injection
- dizziness
- weakness or tiredness
- metallic taste
- blurred vision
- skin problems such as itchiness and rash
- trouble sleeping

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- unusual tiredness or weakness
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- blood in urine
- increased or decreased need to urinate
- skin problems such as itchiness, rash with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints

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- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- chest pain
- shortness of breath
- high blood pressure
- water retention, swelling
- bleeding or bruising more easily than normal
- depression, confusion or anxiety
- bone fracture of the hip, wrist or spine (mainly a risk in people who take high doses of PPIs or use them long term (a year or longer))
- symptoms such as dizziness, fatigue, delirium, seizures, abnormal or fast heartbeat or jerking/shaking movements. These can be a sign of low magnesium levels in your blood
- severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea

The above list includes serious side effects that may require medical attention. Serious side effects are rare. Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After using Pantoprazole - AFT

Storage

Normally your doctor will provide your Pantoprazole-AFT Injection. If, however, you do take your Pantoprazole-AFT Injection from the pharmacy to your doctor, it is important to store it in a safe place away from heat (below 25 °C) and away from light. Do not leave your Pantoprazole-AFT Injection in a car.

When taking Pantoprazole-AFT Injection to home, always ensure that it is stored in a place where children cannot reach it i.e. a locked cupboard at least one-and-a-half meters (5 feet) above the ground is a good place to store medicine.

Disposal

If your doctor stops treating you with Pantoprazole-AFT injection, your hospital pharmacist will dispose of any unused medicine.

Product description

What it looks like

Pantoprazole-AFT Injection is available as 40 mg injection.

Pantoprazole-AFT Injection is a white to off-white powder provided in a glass vial.

Ingredients

The active ingredient in Pantoprazole- AFT Injection is pantoprazole. The inactive ingredients are mannitol and tribasic sodium phosphate dodecahydrate

Supplier

AFT Pharmaceuticals Ltd.
Auckland, New Zealand

This leaflet was revised in January 2024.