

I-Pantoprazole

Pantoprazole (as sodium sesquihydrate) delayed release tablets

Consumer Medicine Information

Please read this information before you start taking this medicine.

What is in this CMI

This leaflet answers some common questions about I-PANTOPRAZOLE. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking I-PANTOPRAZOLE against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What is I-PANTOPRAZOLE used for

Ulcers

I-PANTOPRAZOLE 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. Most people who have a peptic ulcer also have bacteria called *Helicobacter pylori* in their stomach. When Somac is taken with antibiotics the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

I-PANTOPRAZOLE may also be used to prevent ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs). These are medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (inflammation of the joints).

Reflux disease

I-PANTOPRAZOLE 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.

I-PANTOPRAZOLE is also used to prevent reflux oesophagitis from coming back.

Zollinger-Ellison syndrome

I-PANTOPRAZOLE 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 this medicine 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 take I-PANTOPRAZOLE

When you must not take it

Do not take I-PANTOPRAZOLE if:

you have an allergy to:

- any medicine containing 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 take this medicine if you have severe liver disease or cirrhosis.

Do not take I-PANTOPRAZOLE in combination with antibiotics or any other medicine if:

- you are allergic to any of the antibiotics or medicines your doctor may prescribe with I-PANTOPRAZOLE.
- you have moderate to severe liver or kidney disease.

Do not take I-PANTOPRAZOLE in combination with atazanavir or nelfinavir (anti-viral medications).

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

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

I-PANTOPRAZOLE should not be given to children.

Safety and effectiveness of I-PANTOPRAZOLE in children have not been established.

Before you start to take it

- **Tell your doctor or pharmacist if you have any 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, intend to become pregnant, or are breast-feeding.** Your doctor can discuss the risks and benefits involved. If you have not told your doctor about any of the above, tell them before you take I-PANTOPRAZOLE.
- **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 and feel weak
 - you notice blood in your stools

Your doctor may need to perform some additional tests before you take I-PANTOPRAZOLE.

Taking other medicines

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

Some medicines & I-Pantoprazole may interfere with each other. These include:

- warfarin, phenprocoumon - medicines used to prevent blood clots (anticoagulants)
- atazanavir, nelfinavir – medicines used to treat viral infections such as HIV
- ketoconazole, itraconazole, posaconazole - medicines used to treat fungal infection
- 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 I-PANTOPRAZOLE, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking I-PANTOPRAZOLE.

How to take I-PANTOPRAZOLE

Follow all directions given to you by your doctor 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 take

The usual dose is 40 mg per day.

However, if your doctor also prescribes antibiotics in combination with I-PANTOPRAZOLE for the treatment of duodenal ulcers, the dose of I-PANTOPRAZOLE is 80 mg per day. The first 40 mg dose should be taken in the morning and the second should be taken before the evening meal for 7 days.

Your doctor will prescribe the dose that is right for you. The dose and frequency of I-PANTOPRAZOLE that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose as your condition changes.

How to take it

Swallow your tablets whole with a little water with or without food.

When to take it

Take I-PANTOPRAZOLE at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you are taking other medicines, like antibiotics, in combination with I-PANTOPRAZOLE therapy, follow the instructions for the use of each medicine carefully.

Do not crush or chew the tablets. I-PANTOPRAZOLE tablets have a special coating to protect them from the acidic contents of your stomach. For I-PANTOPRAZOLE to work effectively, this coating must not be broken.

How long to take it

Continue taking your medicine for as long as your doctor or pharmacist tells you.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice (13 11 26), or go to Accident and Emergency at your nearest hospital, if you or anyone else may have taken too much I-PANTOPRAZOLE. Do this even if there are no signs of discomfort or poisoning.

Urgent medical attention may be needed.

While you are taking I-PANTOPRAZOLE

Things you must do

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking I-PANTOPRAZOLE.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

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.

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 you must NOT do

Do not use I-PANTOPRAZOLE to treat any other complaints unless your doctor tells you to.

Do not give I-PANTOPRAZOLE to anyone else, even if they have the same symptoms as you.

Things that may help your condition

Some self help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- **Alcohol:** your doctor may advise you to limit your alcohol intake.
- **Aspirin and many other medicines used to treat arthritis, period pain, headaches:** these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.
- **Caffeine:** your doctor may advise you to limit the number of drinks which contain

caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.

- **Eating habits:** eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- **Smoking:** your doctor may advise you to stop smoking or at least cut down.
- **Weight:** your doctor may suggest losing some weight to help your condition.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking I-PANTOPRAZOLE.

It helps most people with peptic ulcers or reflux disease, but it may have unwanted side effects in a few people.

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

Ask your doctor any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

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

These are the more common side effects of I-PANTOPRAZOLE.

Tell your doctor immediately 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 the urine
- increased or decreased need to urinate
- skin problems such as itchiness and rash with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints.
- 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 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 that is making you feel unwell. Other side effects not listed above may occur in some people.

Ask your doctor or pharmacist if you do not understand some of the information in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking I-PANTOPRAZOLE

Storage

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep I-PANTOPRAZOLE tablets in a cool dry place where the temperature stays below 25°C.

Do not store I-PANTOPRAZOLE or any other medicines in a bathroom, near a sink or window sills. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep I-PANTOPRAZOLE where children cannot reach it.

A locked cupboard at least one-and-a-half metres (5 feet) above the ground, is a good place to store medicines.

Disposal

If your doctor tells you to stop taking I-PANTOPRAZOLE or if the medicines have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What it looks like

I-PANTOPRAZOLE is available as 40 mg tablets. The tablets have an acid-resistant coating called an enteric coating.

The 40 mg tablets are yellow and oval shaped, plain on both sides.

I-PANTOPRAZOLE 40 mg tablets are available in blister packs 30 tablets.

Active ingredients:

Each tablet of I-PANTOPRAZOLE contains the equivalent of 40 mg pantoprazole

Other ingredients:

- Mannitol
- Sodium carbonate anhydrous
- Sodium starch glycolate
- Crospovidone
- Silica-colloidal anhydrous
- Calcium stearate
- Hypromellose
- Macrogol 6000
- Purified water,
- Sodium hydroxide
- Eudragit L30-D55
- Opadry AMB Aqueous Moisture Barrier Coating System 80W52172 Yellow

I-PANTOPRAZOLE tablets do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

Name and Address of the sponsor

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