

TOPRA™ 40

Pantoprazole (as sodium sesquihydrate) 40 mg enteric-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TOPRA.

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 taking TOPRA 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 TOPRA is used for

The name of your medicine is TOPRA. It contains the active ingredient called pantoprazole.

Ulcers

TOPRA 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 TOPRA is taken with antibiotics the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

TOPRA 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

TOPRA 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.

TOPRA is also used to prevent reflux oesophagitis from coming back.

Zollinger-Ellison syndrome

TOPRA 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.

Other uses

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

How TOPRA works

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

TOPRA 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.

There 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 TOPRA

When you must not take it

Do not take TOPRA if you have an allergy to:

- pantoprazole; or
- 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 TOPRA in combination with antibiotics or any other medicine if:

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

Do not take TOPRA in combination with atazanavir (an anti-viral medication). 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 has expired or is damaged return it to your pharmacist for disposal.

TOPRA should not be given to children.

There is insufficient data concerning the safety and effectiveness of TOPRA in children.

If you are not sure whether you should start taking TOPRA alone, or TOPRA in combination with antibiotics, talk to your doctor.

Before you start to take it

You must tell your doctor if you have any allergies to:

- Pantoprazole;
- any of the ingredients listed at the end of this leaflet; or
- any other medicines, or any other substances, such as foods, preservatives or dyes.

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 TOPRA.

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; or
- you notice blood in your stools.

Your doctor may need to perform some additional tests before you take TOPRA.

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 and TOPRA 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 TOPRA, 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 TOPRA.

How to take it

Follow all direction 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 take

The usual dose is 40 mg per day.

However, if your doctor also prescribes antibiotics in combination with TOPRA for the treatment of duodenal ulcers, the dose of TOPRA 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.

As the 20 mg dose of TOPRA is not marketed, alternative brands of pantoprazole should be used.

Your doctor will prescribe the dose that is right for you.

The dose and frequency of TOPRA that your doctor prescribes for you depends on your medical condition.

Your doctor may change the dose as your condition changes.

How and when to take it

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

Take TOPRA 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 TOPRA therapy, follow the instructions for the use of each medicine carefully.

Do not crush or chew the tablets. TOPRA tablets have a special coating to protect them from the acidic contents of your stomach. For TOPRA 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 are not sure what to do, as your doctor or pharmacist.

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 Poisons Information Centre (telephone Australia 13 11 26 or in New Zealand is 0800 POISON or 0800 764 766), or go to Accident and Emergency (Casualty) at your nearest hospital, if you or anyone else may have taken too much TOPRA. Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be needed.

While you are taking it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TOPRA.

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

If you are going to have surgery, tell the surgeon that 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 this medicine to treat any other complaints unless your doctor tell you to.

Do not give this medicine 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.

Talk to your doctor or pharmacist about these measures and for more information.

- **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 have any problems while taking TOPRA

It helps most people 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 or pharmacist 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;
- blurred vision;
- skin problems such as itchiness and rash; or
- trouble sleeping.

These are the more common side effects of TOPRA. Some of these side effects may be due to the combination of other medicines you are taking with TOPRA.

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, or swelling, blistering or peeling of the skin;
- 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 seizure, abnormal or fast heartbeat or jerking/shaking movements. These can be a sign of low magnesium levels in your blood; or
- 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 urgent 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 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 it

Storage

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

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

Keep TOPRA in a cool dry place where the temperature stays below 25°C.

Do not store TOPRA or any other medicines in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep TOPRA where children cannot reach it.

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

Disposal

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

Product description

What it looks like

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

TOPRA 40

Yellow coloured, enteric-coated, oval biconvex tablets.

Ingredients

Active ingredient

The active ingredient in TOPRA 40 is pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

Inactive ingredients

- mannitol;
- crospovidone;

- sodium carbonate anhydrous;
- hydroxypropylcellulose;
- calcium stearate;
- hypromellose;
- iron oxide yellow (CI 77492);
- methacrylic acid - ethyl acrylate copolymer (1:1); and
- triethyl citrate.

TOPRA tablets do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

Australian registration numbers

40 mg enteric-coated tablets (in blister packs): AUST R 191581

40 mg enteric-coated tablets (in bottles): AUST R 191578

*Some of these presentations and pack sizes are not marketed.

Sponsor/Marketing Authorisation Holder

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