

Ranitidine Sandoz®

ranitidine hydrochloride film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ranitidine Sandoz.

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 risk of you taking this medicine against the benefits they expect it will 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 Ranitidine Sandoz is used for

This medicine is used to treat:

- Treat stomach and duodenal ulcer disease (also known as peptic 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 produced in the stomach. Ranitidine Sandoz is also used to help stop these ulcers from coming back.
- Stop these ulcers from coming back
- 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
- Treat Zollinger-Ellison syndrome, a rare condition where the stomach produces very large amounts of acid, much more than in ulcers and reflux disease.
- Treat Scleroderma oesophagitis. Scleroderma is a rare condition, and in scleroderma oesophagitis the food pipe is abnormal and reflux occurs.

It contains the active ingredient ranitidine hydrochloride. Ranitidine hydrochloride belongs to a group of medicines called H2 antagonists or H2 blockers.

It works by decreasing the amount of acid made by the stomach. This helps to reduce the pain and also allows the ulcer and/or reflux disease to heal in most people.

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 reason.

There is no evidence that Ranitidine Sandoz is addictive.

Before you take Ranitidine Sandoz

When you must not take it

Do not take this medicine if you have an allergy to:

- ranitidine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description
- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take 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 of the following medical conditions:

- acute porphyria, an inherited blood condition
- stomach cancer
- stomach ulcers before and you are taking NSAID medicines
- kidney problems
- liver problems
- lung disease
- diabetes
- over 65 years of age
- any condition where your immune system may be affected.

Tell your doctor if you have had to stop taking this or any other medicine for your ulcer or reflux.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Ranitidine Sandoz.

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 or health food shop.

Some medicines and Ranitidine Sandoz may interfere with each other. These include:

- sucralfate, another medicine used to treat ulcers
- warfarin, a medicine used to prevent blood clots
- triazolam and midazolam, medicines used as sedatives
- ketoconazole, an anti-fungal medicine
- atazanavir and delavirdine, medicines used to treat HIV
- glipizide, a medicine used for diabetics
- gefitinib, a medicine used in the treatment of cancer
- NSAID medicines, for pain and inflammation

- Procainamide or n-acetylprocainamide, used to treat heart problems.

These medicines may be affected by Ranitidine Sandoz 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 taking this medicine.

How to take Ranitidine Sandoz

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, ask your doctor or pharmacist for help.

How much to take

The dosage of Ranitidine Sandoz depends on the condition it is being used to treat. The usual adult dosage range is 150mg to 300mg per day, taken as one 150mg tablet once or twice a day or one 300mg tablet at bed time. The treatment of Zollinger-Ellison syndrome may require higher doses.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Ranitidine Sandoz may not work as well and your problem may not improve.

How to take it

If you need to break Ranitidine Sandoz, hold the tablet with both hands and snap along the break line.

When to take Ranitidine Sandoz

It does not matter whether you take the tablets before or after food.

How long to take Ranitidine Sandoz

The duration of treatment with Ranitidine Sandoz depends on the condition it is being used to treat.

Your pain or other symptoms may take a few days to go away. Take all the tablets your doctor has prescribed for you, even if you feel better.

Your doctor may decide to continue your treatment with Ranitidine Sandoz, possibly at a different dosage range, in order to prevent the problem from coming back again.

Use in children

Ranitidine Sandoz has not been studied fully in children. However, it has been used successfully in children aged 8 to 18 years in doses up to 150mg twice daily. Your child's doctor will discuss the risks and benefits of your child taking Ranitidine Sandoz.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

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

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, ask 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 the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Ranitidine Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Ranitidine Sandoz

Things you must do

Always follow your doctor's instructions carefully.

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

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

Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take Ranitidine Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Ranitidine Sandoz affects you.

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

Be careful when drinking alcohol while you are taking this medicine.

If you drink, alcohol dizziness or light-headedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ranitidine Sandoz.

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 or pharmacist to answer any questions you may have.

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

- constipation, diarrhoea, nausea (feeling sick) and vomiting
- abdominal pain or discomfort.

These are the more common side effects of Ranitidine Sandoz. Mostly, these are mild and short-lived.

- breast tenderness and/or breast enlargement
- breast discharge
- headache, sometimes severe
- hair loss
- sexual problems
- tiredness or difficulty sleeping
- dizziness or drowsiness
- muscle and joint pain
- abnormal uncontrolled movements, muscle twitching or spasms.

These are rare side effects of Ranitidine Sandoz.

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

- yellowing of the skin or eyes (jaundice)
- confusion, depression and hallucination
- general illness associated with weight loss
- blurred vision
- skin rash
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the limbs, face, lips, mouth or throat which may cause difficulty in swallowing or breathing, itchy rash or hives. These are the symptoms of an allergic reaction.
- severe upper stomach pain together with nausea and vomiting or a change in the type of pain wheezing, chest pain or tightness, unusual heart beat (fast, slow or irregular).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Ranitidine Sandoz

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

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

Do not store Ranitidine Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Ranitidine Sandoz 150mg - yellow, round, film-coated tablets, scored on one side.

Available in blisters of 60 tablets.

Ranitidine Sandoz 300mg - yellow, oblong, film-coated tablets, scored on one side.

Available in blisters of 30 tablets.

Ingredients

Active ingredient:

- Ranitidine Sandoz 150mg - 150mg ranitidine as ranitidine hydrochloride
- Ranitidine Sandoz 300mg - 300mg ranitidine as ranitidine hydrochloride

Inactive ingredients:

- microcrystalline cellulose
- calcium hydrogen phosphate
- maize starch
- sodium starch glycolate type A
- magnesium stearate
- colloidal anhydrous silica
- lactose monohydrate
- hypromellose
- titanium dioxide
- macrogol 4000
- iron oxide yellow.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369
Novartis New Zealand Ltd
PO Box 99102
Newmarket
Auckland 1149
New Zealand
Tel: 0800 354 335

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150mg film-coated tablets: AUST R 70325

300mg film-coated tablets: AUST R 70356