

Ranitidine Sandoz® Injection

ranitidine hydrochloride injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ranitidine Sandoz Injection.

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 having Ranitidine Sandoz Injection 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 Injection is used for

The name of your medicine is Ranitidine Sandoz Injection. It contains the active ingredient ranitidine (as hydrochloride).

Ranitidine Sandoz Injection is used to treat a variety of conditions. If you are unsure why you have been prescribed Ranitidine Sandoz Injection, talk to your doctor.

Ranitidine Sandoz Injection is used to treat 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 made in the stomach.

Ranitidine Sandoz Injection is also used to help stop ulcers from coming back.

Ranitidine Sandoz Injection is 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.

Ranitidine Sandoz Injection is also 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.

Ranitidine Sandoz Injection may be used to treat scleroderma oesophagitis. Scleroderma is a rare condition, and in scleroderma oesophagitis the food pipe is abnormal and there is reflux.

Ask your doctor if you have any questions about why Ranitidine Sandoz Injection was prescribed for you.

Your doctor may have prescribed it for another reason.

How Ranitidine Sandoz Injection works

Ranitidine Sandoz Injection 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 reduce the pain and also allows the ulcer to heal in most people.

There is no evidence that Ranitidine Sandoz Injection is addictive.

Before you are given Ranitidine Sandoz Injection

When you must not be given it

Do not use Ranitidine Sandoz Injection if:

- you are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description
- it is past its expiry date or the packaging appears to have been tampered with.

Before you are given it

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as ranitidine
- any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or will be breast feeding while you are using Ranitidine Sandoz Injection.

Ranitidine passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of using Ranitidine Sandoz Injection during pregnancy and breastfeeding.

Tell your doctor if you are over 40 years of age, and it is the first time you have experienced symptoms of reflux or indigestion, or that these symptoms have recently changed.

Tell your doctor if you have or have had any of the following medical conditions:

- peptic, duodenal, or stomach ulcer
- symptoms like vomiting, diarrhoea, passage of blood, "coffee ground" like substance in vomit or faeces, or unintended weight loss
- acute porphyria, an inherited blood condition
- stomach cancer
- stomach ulcers before and you are taking NSAID medicines
- kidney problems
- liver problems
- lung disease
- diabetes
- heart disease
- over 65 years of age
- any condition where your immune system may be affected.

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

Taking other medicines

Tell your doctor if you are taking any other medicine, 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 reflux and 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 diabetes
- 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 Injection, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines.

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

How Ranitidine Sandoz Injection is given

The injection will be administered by your doctor or a nurse.

The usual dose is 50 milligrams of ranitidine every six to eight hours either by injection into a vein or through a 'drip'.

Use in children

Ranitidine Sandoz Injection 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 Injection.

If you are given too much (overdose)

As your doctor is administering the dose, overdose is unlikely to occur. However, if at any time you do not feel well and are worried, 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 your nearest hospital, if you think you or anyone else may have been given too much Ranitidine Sandoz Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being treated with Ranitidine Sandoz Injection

Things you must do

- Always follow your doctors instructions carefully.
- Tell your doctor if you become pregnant while being treated with Ranitidine Sandoz Injection.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Ranitidine Sandoz Injection.

Things to be careful of

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

Ranitidine Sandoz Injection 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 given this medicine.

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

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 similar medicines used to treat arthritis, period pain or headaches - these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist can 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 -

if you are overweight, your doctor may suggest losing some weight to help your condition.

Side effects

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

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 side effects.

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

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 Injection. Mostly, these are mild and short-lived.

- breast tenderness and/or breast enlargement
- breast discharge
- headache, sometimes severe
- hair loss
- sexual problems
- tiredness, dizziness or drowsiness, insomnia (sleeplessness)
- muscle and joint pain
- pain or flaking skin where you had the injection
- abdominal uncontrolled movements, muscle twitching or spasms.

These are rare side effects of Ranitidine Sandoz Injection.

Tell your doctor or pharmacist immediately if you notice any of the following:

- chest infection
- depression, hallucination or mental confusion
- general illness associated with weight loss
- blurred vision
- skin troubles such as rash (red spots), itching, skin lumps or hives
- yellowing of the skin and/or eyes, also called jaundice
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal.

These are serious side effects of Ranitidine Sandoz Injection. You may need urgent medical attention. Serious side effects are rare.

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

- swelling of the face, eyelids, lips, mouth or throat, which may cause difficulty in swallowing or breathing, itchy skin 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).

These are very serious side effects. You may need urgent medical attention or hospitalisation. All these side effects are rare.

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

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

Some health problems or complications may arise from the condition being treated itself. For this reason, contact your doctor immediately if you notice any of the following:

- ongoing stomach pain or indigestion
- passing black or blood-stained motions
- vomiting
- unexpected weight loss.

After using Ranitidine Sandoz Injection

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. Protect from light.

Do not store Ranitidine Sandoz Injection 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.

The solution for injection should be clear and colourless to pale yellow in colour. The injection should not be used if it is discoloured or cloudy.

Product description

What it looks like

Ranitidine Sandoz Injection: brown glass ampoules containing a solution for injection. Available in boxes of five ampoules.

Ingredients

Active ingredient:

Each 5mL ampoule contains 50mg of ranitidine (as hydrochloride).

Inactive ingredient:

- water for injection
- sodium hydroxide.

Supplier

Ranitidine Sandoz Injection is supplied in Australia by:

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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