

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Roxithromycin 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 ROXITHROMYCIN SANDOZ IS USED FOR

This medicine is used to treat various infections caused by bacteria such as:

- acute pharyngitis (sore throat and discomfort when swallowing)
- tonsillitis
- sinusitis
- acute bronchitis (infection of the bronchi causing coughing)
- exacerbation of chronic bronchitis
- pneumonia (lung infection characterised by fever, malaise, headache)
- skin and soft tissue infections
- non gonococcal urethritis
- impetigo (bacterial infection causing sores on the skin).

It contains the active ingredient roxithromycin. Roxithromycin belongs to a group of medicines called macrolides.

It works by killing or stopping the growth of the bacteria that are causing the infection.

However, Roxithromycin Sandoz does not have any effect on viral infections such as the flu.

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.

This medicine is not addictive.

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

BEFORE YOU TAKE ROXITHROMYCIN SANDOZ

When you must not take it

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

- roxithromycin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other macrolide antibiotic (such as azithromycin, clarithromycin or erythromycin).

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 if you have severe problems with your liver.

Do not take this medicine if you are also taking certain medicines for migraine headache of the group of ergot alkaloids (such as Migral®, Cafergot®, Ergodryl®, Dihydroergot®).

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:

- impaired kidney function
- problems with your liver (hepatic cirrhosis with jaundice and/or ascites).

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

This medicine is not recommended for use during pregnancy.

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

Tell your doctor if you are breastfeeding or planning to breastfeed.

Roxithromycin passes into breast milk

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

Tell your doctor or pharmacist if you plan to have surgery.

If you have not told your doctor about any of the above, tell him/her before you start taking Roxithromycin 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 Roxithromycin Sandoz may interfere with each other. These include:

- theophylline, a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine or dihydroergotamine
- disopyramide, a medicine used to treat irregular heart rhythms
- terfenadine and astemizole, medicines used to treat allergies
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- midazolam, a medicine used to induce sleep before operations
- cyclosporin, a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- cisapride, a medicine used to treat gastrointestinal problems

- pimozone, an antipsychotic medicine.

These medicines may be affected by Roxithromycin 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 ROXITHROMYCIN 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 recommended dosage for adults is 300mg per day.

You may take this according to one of the following dosage regimens:

- one 300mg tablet once a day, or
- one 150mg tablet twice a day, or
- two 150 mg tablets once a day.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.

The dose for a child will depend on the child's weight.

The recommended dose for children weighing 40kg and more is 150mg twice a day.

Roxithromycin Sandoz should not be used for children less than 40kg in weight.

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, Roxithromycin Sandoz may not work as well and your problem may not improve.

How to take it

Roxithromycin Sandoz tablets should be swallowed whole with a glass of water.

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

When to take Roxithromycin Sandoz

Take your medicine 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.

Take your medicine on an empty stomach, for example, at least 15 minutes before food or at least 3 hours after food.

Food can interfere with the absorption of this medicine.

How long to take Roxithromycin Sandoz

Roxithromycin Sandoz is usually taken for 5 to 10 days for treating infections. Your doctor may want you to take Roxithromycin Sandoz for a longer period.

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

It is important to keep taking your medicine even if you feel well.

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 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 that you or anyone else may have taken too much Roxithromycin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING ROXITHROMYCIN SANDOZ

Things you must do

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

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 or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

Tell your doctor immediately if you get severe diarrhoea. Do this even if it occurs several weeks after Roxithromycin Sandoz has been stopped.

Diarrhoea may be a sign for a serious condition affecting your bowel. You may need urgent medical attention. Check with your doctor before taking any diarrhoea medication.

Tell your doctor or pharmacist if you get vaginal itching or discharge.

Tell your doctor or pharmacist if you get a sore, white mouth or tongue while or shortly after taking Roxithromycin Sandoz.

These could be the symptoms of a fungal/yeast infection called thrush. The use of Roxithromycin Sandoz can allow fungi/yeast to grow and cause the above symptoms. Roxithromycin Sandoz is not effective against fungi/yeast.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Roxithromycin 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.

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

If you stop taking Roxithromycin Sandoz too early, not all of the bacteria might be killed. The remaining could start to grow again and prevent your infection from clearing completely or even cause it to return.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Roxithromycin 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:

- oral thrush with a white, furry, sore tongue and mouth
- vaginal thrush with a sore and itchy vagina and/or discharge
- nausea, vomiting, stomach pain, diarrhoea, flatulence, loss of appetite
- red and/or itchy skin, skin rash
- headache, tiredness, dizziness, pins and needles, ringing in the ears
- hallucinations
- altered taste and/or smell.
- Blurred vision and /or visual impairment

These are mild side effects of the medicine, and are short-lived.

Tell your doctor as soon as possible if you notice any of the following, in particular if they occur several weeks after you finished taking Roxithromycin Sandoz:

- severe abdominal or stomach cramps
- watery and severe diarrhoea, which may even be bloody
- fever, in combination with one or both of the above.

The above list includes serious side effects of Roxithromycin Sandoz. These side effects are rare. You may suffer from a serious condition affecting your bowel requiring medical attention.

Check with your doctor before taking any diarrhoea medication.

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

- severe persistent diarrhoea
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- swelling of the face, lips, mouth and tongue
- difficulty in swallowing or breathing
- an allergic reaction (for example, itchy skin, rash, swelling, asthma or wheezing)
- severe skin rash.

- Sever blisters and bleeding in the lips, eyes, mouth, nose and genitals

The above list includes very serious side effects. If you have them, you may have had a serious allergic reaction to Roxithromycin Sandoz. You may need urgent medical attention or hospitalisation. These side effects are very 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 ROXITHROMYCIN 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 Roxithromycin 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

Roxithromycin Sandoz comes in two types of tablets:

Roxithromycin Sandoz 150mg - white, round, convex film-coated tablets, scored on one side, embossment R150 on the other side.

Available in blister packs of 10 tablets.

Roxithromycin Sandoz 300mg - white, round, convex film-coated tablets, scored on one side, embossment R300 on the other side.

Available in blister packs of 5 tablets.

Ingredients

Active ingredient:

- Roxithromycin Sandoz 150mg - 150mg roxithromycin
- Roxithromycin Sandoz 300mg - 300mg roxithromycin

Inactive ingredients:

- microcrystalline cellulose
- povidone K30
- croscarmellose sodium
- precipitated silica
- lactose
- hypromellose
- titanium dioxide
- magnesium stearate
- macrogol 4000
- poloxamer 188.

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

Supplier

Roxithromycin Sandoz 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 Limited
PO Box 99102
Newmarket Auckland 1149
New Zealand
Tel: 0800 354 335

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Australian Register Numbers:

Roxithromycin Sandoz 150mg film-coated tablets: AUST R 100989

Roxithromycin Sandoz 300mg film-coated tablets: AUST R 101028