

Roxithromycin-RL™

Roxithromycin Film-Coated Tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Roxithromycin-RL.

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 Roxithromycin-RL against the benefits it 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 want to read it again.

WHAT ROXITHROMYCIN-RL IS USED FOR

The name of your medicine is Roxithromycin-RL. It contains the active ingredient roxithromycin.

Roxithromycin-RL is used to treat various infections caused by bacteria. For example:

- Acute pharyngitis (sore throat and discomfort when swallowing).
- Tonsillitis.
- Sinusitis.
- Acute bronchitis (infection of the bronchi causing coughing).
- Pneumonia (lung infection characterised by fever, malaise, headache).
- Skin and soft tissue infections.
- Non gonococcal urethritis.
- Impetigo (bacterial infection causing sores on the skin).

Your doctor may have prescribed Roxithromycin-RL for another reason. Ask your doctor if you have any questions about why Roxithromycin-RL was prescribed for you.

How Roxithromycin-RL works

Roxithromycin-RL 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-RL does not have any effect on viral infections such as the flu.

There is no evidence that Roxithromycin-RL is addictive.

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

BEFORE YOU TAKE ROXITHROMYCIN-RL

When you must not take Roxithromycin-RL

Do not take Roxithromycin-RL if:

- You are allergic to roxithromycin or any other macrolide antibiotic eg azithromycin, clarithromycin or erythromycin.
- You are allergic to 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.
- You are pregnant or breastfeeding, unless permitted by your doctor.
- You have severe problems with your liver.
- You are taking certain medicines for migraine headache of the group of ergot alkaloids (eg Migral, Cafergot, Ergodryl, Dihydergot; [not all brands listed]).

Before you start to take Roxithromycin-RL

Tell your doctor if you have allergies to:

- Any other medicines, especially if they are in the same drug class as roxithromycin.
- Any other substances, including foods, preservatives or dyes.

Tell your doctor if you plan on becoming pregnant while you are using Roxithromycin-RL.

Tell your doctor if you are breastfeeding or plan to breastfeed. Roxithromycin-RL passes into the breast milk. Your doctor will discuss the risks and benefits of using Roxithromycin-RL while breastfeeding.

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

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

Taking other medicines

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

In particular, tell your doctor if you take any of the following:

- Theophylline (Neulin, Austyn, Theo-dur), a medicine used to treat asthma.
- Certain medicines for migraine headache such as ergotamine (Migral, Ergodryl, Cafergot) or dihydroergotamine (Dihydroergot tablets).
- Disopyramide (Rythmodan), a medicine to treat irregular heart rhythms.
- Terfenadine (Teldane) and astemizole (Hismanal), over the counter medicines used to treat allergies.
- Warfarin (Coumadin, Marevan), a medicine used to prevent blood clots.
- Digoxin (Lanoxin), a medicine used to treat heart failure.
- Midazolam (Hypnovel), a medicine used to induce sleep before operations.
- Cyclosporin (Neoral, Sandimmun), a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system.
- Cisapride (Prepulsid), a medicine used to treat gastrointestinal problems.
- Pimozide (Orap), an antipsychotic medicine.

These medicines may be affected by Roxithromycin-RL, 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 will advise you.

HOW TO TAKE ROXITHROMYCIN-RL

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

The dosage of Roxithromycin-RL for children depends on their weight.

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

Roxithromycin-RL should not be used for children less than 40 kg in weight. However, your doctor might advise you to take a different dose depending on your condition and your reaction to the medicine.

No dose adjustment is required for the use in elderly.

Roxithromycin-RL is usually taken for 5 to 10 days for treating infections. Your doctor may want you to take Roxithromycin-RL for a longer period. Ask your doctor for advice if you are not sure how long you should be taking it.

Continue to take Roxithromycin-RL until the pack is finished or your doctor tells you to stop.

Roxithromycin-RL should be taken on an empty stomach to work best. Take Roxithromycin-RL at least 15 min before or at least 3 hours after a meal. Roxithromycin-RL tablets should be swallowed whole with a glass of water

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

If you forget to take your dose

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 you missed.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Roxithromycin-RL.

Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE USING ROXITHROMYCIN-RL

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while taking Roxithromycin-RL.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Roxithromycin-RL.
- Tell your doctor if the symptoms of your infection do not improve within a few days or worsen.

- Tell your doctor immediately if you get severe diarrhoea. Do this even if this occurs several weeks after you have

finished taking Roxithromycin-RL. Diarrhoea may be a sign for a severe condition affecting your bowel. You may need urgent medical care.

- Check with your doctor before taking any diarrhoea medication.
- Tell your doctor or pharmacist if you get a sore, white mouth or tongue while or shortly after taking Roxithromycin-RL.
- Tell your doctor or pharmacist if you get vaginal itching or discharge. These could be the symptoms of a fungal/yeast infection called thrush. The use of Roxithromycin-RL can allow fungi/yeast to grow and cause the above symptoms. Roxithromycin-RL is not effective against fungi/yeast.

Things you must not do

- Do not stop taking Roxithromycin-RL without your doctor's permission. If you stop taking Roxithromycin-RL 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.
- Do not use Roxithromycin-RL to treat any other complaint unless your doctor says so.
- Do not give this medication to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how Roxithromycin-RL affects you. Roxithromycin-RL may cause dizziness or light-headedness in some people, especially after the first dose.

SIDE EFFECTS

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor 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.
- Red and/or itchy skin.
- Headache, tiredness, dizziness, ringing in the ears.
- Loss of appetite.
- Altered taste.
- Tiredness.

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

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

- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Severe persistent diarrhoea.
- An allergic reaction, as itchy skin, rash, swelling, asthma.

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

Tell your doctor immediately if you notice any of the following, in particular if they occur several weeks after you finished taking Roxithromycin-RL:

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

These may be rare but serious side effects of Roxithromycin-RL. You may suffer from a serious condition affecting your bowel. You may need urgent medical attention. Do not take any medicine for diarrhoea without first asking your doctor.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

AFTER USING ROXITHROMYCIN-RL

Storage

Keep Roxithromycin-RL in the original packaging until you need to take it.

Store below 25 degrees C in a dry place, out of the reach of children.

Disposal

Return any unused or out of date medicine to your pharmacist.

PRODUCT DESCRIPTION

What Roxithromycin-RL looks like

Roxithromycin-RL 150mg tablets: white, round, convex film-coated tablets, scored on one face and embossed R 150.

Available in blister packs of 10 tablets.

Roxithromycin-RL 300mg tablets: white, round, convex film-coated tablets, scored on one face and embossed R 300.

Available in blister packs of 5 tablets.

Ingredients

Active Ingredient

Each Roxithromycin-RL 150mg film-coated tablet contains 150mg roxithromycin.

Each Roxithromycin-RL 300mg film-coated tablet contains 300mg roxithromycin.

Inactive Ingredients

Each Roxithromycin-RL tablet also contains microcrystalline cellulose, povidone, croscarmellose sodium, silicon dioxide, lactose, hypromellose, titanium dioxide, magnesium stearate, macrogol 4000 and poloxamer.

Supplier

Roxithromycin-RL is supplied in Australia by:

Real-RL

A Division of

GlaxoSmithKline Australia Pty Ltd

1061 Mountain Highway

Boronia Victoria 3155

This leaflet was prepared on 18 December 2006.

Australian Register Numbers:

Roxithromycin-RL 150mg film-coated tablets: AUST R
129648 (blisters)

Roxithromycin-RL 300mg film-coated tablets: AUST R
129649 (blisters)

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