

Roximycin

contains the active ingredient roxithromycin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Roximycin.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Roximycin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Roximycin is used for

Roximycin is used to treat infections in different parts of the body caused by bacteria. For example:

- 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)

Roximycin is an antibiotic that belongs to a group of medicines called macrolides. These antibiotics work by killing or stopping the growth of the bacteria that are causing your infection.

Roximycin, like other antibiotics, does not work against viral infections such as the flu.

Ask your doctor if you have any questions about why Roximycin has been prescribed for you.

Your doctor may have prescribed Roximycin for another reason.

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

Roximycin is not addictive.

Before you take Roximycin

When you must not take it

Do not take Roximycin if:

1. **you have an allergy to:**
 - roxithromycin or any other macrolide antibiotic eg. azithromycin (Zithromax), clarithromycin (eg. Klacid, Kalixocin) or erythromycin (eg. EES, E-Mycin)
 - any of the ingredients listed at the end of this leaflet (see Product description)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.

2. **you have severe liver problems**
3. **you are taking certain medicines for migraine headache called ergot alkaloids (eg. Cafergot, Dihyergot)**
Ask your doctor if you are not sure if you are taking one of these medicines.
4. **the packaging is torn or shows signs of tampering**
5. **the expiry date (EXP) on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work as well.

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

Before you start to take it

Tell your doctor if:

1. **you are pregnant or intend to become pregnant**
Your doctor will discuss the risks and benefits of using Roximycin during pregnancy.
2. **you are breast-feeding or plan to breast-feed**
Roximycin passes into the breast milk. Your doctor will discuss the risks and benefits of using Roximycin while breast-feeding.
3. **you have or have ever had any other health problems/medical conditions, including:**
 - kidney problems (impaired function)
 - liver problems (hepatic cirrhosis with jaundice and/or ascites)
 - congenital prolongation of the QT interval, with ongoing proarrhythmic heart conditions

4. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell him/her before you take Roximycin.

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.

There may be interference between Roximycin and some other medicines, including:

- theophylline (Nuelin), a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine (Cafergot) or dihydroergotamine (Dihyergot)
- disopyramide (Rythmodan), a medicine to treat irregular heart rhythms
- terfenadine and astemizole, 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), 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 stomach reflux
- pimozide (Orap), an antipsychotic medicine
- antiarrhythmic agents

These medicines may be affected by Roximycin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Roximycin.

How to take Roximycin

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 on the pack, ask your doctor or pharmacist.

How much to take

The recommended adult dose is 300 mg per day which may be taken according to one of the following regimens:

- one 300 mg tablet once a day or
- one 150 mg 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 children will depend on the child's weight. Your doctor will tell you how much Roximycin your child should take.

How to take Roximycin

Swallow the tablet whole with a glass of water.

When to take Roximycin

Take Roximycin at least 15 minutes before food or on an empty stomach (i.e. more than 3 hours after a meal).

Roximycin works best if you take it on an empty stomach. Food in the stomach can reduce the absorption of Roximycin.

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.

How long to take Roximycin for

Keep taking Roximycin until you finish the pack, or for as long as your doctor recommends.

Roximycin is usually taken for 5 to 10 days.

Do not stop taking Roximycin, even if you feel better after a few days, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you forget to take Roximycin

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 your tablets as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

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

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

If you take too much Roximycin (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Roximycin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Roximycin

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Roximycin.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Roximycin.

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

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Roximycin.

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea, tell your doctor immediately. Do this even if it occurs several weeks after Roximycin has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Do not take any anti-diarrhoea medicine without first checking with your doctor.

If you get a sore, white mouth or tongue while taking, or soon after stopping Roximycin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes, the use of Roximycin allows fungi/yeast to grow and the above symptoms to occur. Roximycin does not work against fungi/yeast.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not stop taking Roximycin, or lower the dose, without checking with your doctor.

If you do not complete the full course prescribed by your doctor, all the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or may return.

Do not use Roximycin to treat any other conditions unless your doctor tells you to.

Do not give Roximycin 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 Roximycin affects you.

This medicine may cause dizziness in some people. If you experience any dizziness, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

Roximycin is generally well tolerated, however, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

See your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- signs of an allergic reaction, eg. swelling of the face, lips, mouth and tongue; difficulty breathing or asthma; itchy skin, rash.

This type of allergy is very serious and requires urgent medical attention.

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

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- nausea, vomiting, stomach pain, diarrhoea, flatulence
- pancreatitis - an inflammation of the pancreas
- loss of appetite
- red and/or itchy skin
- hallucinations
- headache, dizziness, ringing in the ears, temporary deafness
- vertigo
- tiredness
- altered taste
- rash

The above list includes the milder side effects of your medicine.

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Roximycin:

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

These are rare but serious side effects. Roximycin can cause some bacteria, which are normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. You may need urgent medical attention.

Do not take any medicine for this diarrhoea without first checking with your doctor.

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
- swelling of the face, lips, mouth and tongue
- difficulty in swallowing and breathing
- an allergic reaction (for example, itchy skin, rash, swelling, asthma)
- severe skin rash

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Roximycin. You may need urgent medical attention or hospitalisation.

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

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients.

After taking Roximycin

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep Roximycin 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.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

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

Do not store Roximycin or any other medicine in the bathroom or near a sink.

Do not leave Roximycin in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Roximycin tablets comes in 2 strengths:

- Roximycin 150 mg - white, round, film coated, biconvex tablets, marked "150" "R" on one side and "G" on the other. Each pack contains 10 tablets.
- Roximycin 300 mg - white, round, film coated, biconvex tablets, marked "300" "R" on one side and "G" on the other. Each pack contains 5 tablets.

Ingredients

Each tablet contains either 150 mg or 300 mg of the active ingredient, roxithromycin.

The tablets also contain the following inactive ingredients:

- povidone
- hydroxypropylcellulose
- maize starch
- poloxamer 188
- colloidal anhydrous silica
- purified talc
- magnesium stearate
- glucose anhydrous
- Opadry white OY-S-58918

The tablets are gluten free.

Supplier

Roximycin is supplied by:
Alphapharm Pty Limited
 (ABN 93 002 359 739)
 Level 1, 30 The Bond,
 30 - 34 Hickson Road,
 Millers Point, NSW 2000,
 Phone: (02) 9298 3999
 www.alphapharm.com.au

Australian registration numbers:

- Roximycin 150 mg
AUST R 99937 (blister pack)
- Roximycin 300 mg
AUST R 99939 (blister pack)

This leaflet was prepared on 5th November 2013.

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