

# APO-Roxithromycin

Roxithromycin

## Consumer Medicine Information

**For a copy of a large print leaflet, Ph: 1800 195 055**

### What is in this leaflet

This leaflet answers some common questions about roxithromycin. 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 using this medicine against the benefits they expect it will have for you.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with your medicine.**

You may want to read it again.

### What this medicine is used for

Roxithromycin is used to treat different infections caused by bacteria, which include:

- acute pharyngitis (sore throat and discomfort when swallowing)
- tonsillitis
- sinusitis
- acute bronchitis (infection of the bronchi causing coughing)
- worsening 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)

#### How it works

Roxithromycin 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.

Roxithromycin, like other antibiotics, does not work against 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 this medicine for another reason.

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

This medicine is not addictive.

This medicine is not recommended for use in children weighing less than 40kg.

### Before you take it

#### When you must not take it

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

- roxithromycin
- any other macrolide antibiotics (e.g. azithromycin, clarithromycin or erythromycin)
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

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

**Do not take this medicine if you have severe liver problems.**

**Do not take this medicine if you are taking certain medicines for migraine headache called ergot alkaloids.**

**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 kidney or liver problems**

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

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

**Tell your doctor if you are planning to have surgery or an anaesthetic.**

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

### ***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 may interfere with each other. These include:

- theophylline, a medicine used to treat asthma
- some medicines for migraine headache called ergot alkaloids
- disopyramide, a medicine to treat irregular heart rhythms
- terfenadine and astemizole, over the counter medicines used to treat allergies
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- midazolam, 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
- rifabutin and bromocriptine (which use the CYP3A liver enzyme).

These medicines may be affected by this medicine 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.

Other medicines not listed above may also interact with roxithromycin.

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## **How to take this medicine**

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**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 box, ask your doctor or pharmacist for help.**

### ***How much to take***

#### **Adults**

The recommended adult dose is 300 mg per day, which may be taken according to one of the following dosage 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 tell you to take a different dose.

#### **Children**

The dose of roxithromycin given to children is dependent upon the child's weight.

The recommended dose for children weighing 40 kg and over is one 150 mg tablet twice daily.

**This medicine is not recommended for use in children weighing less than 40 kg.**

### ***How to take it***

Swallow the tablets whole with a full glass of water.

### ***When to take it***

**Roxithromycin should be taken at least 15 minutes before food or on an empty stomach (i.e. more than 3 hours after a meal).**

**Roxithromycin works best if you take it on an empty stomach.**

### ***How long to take it for***

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

For treating infections, roxithromycin is usually taken for 5 to 10 days.

However, your doctor may prescribe roxithromycin for longer periods.

**Check with your doctor if you are not sure how long to take this medicine for.**

### ***If you forget to take it***

**If it is almost time to take 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, then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you experiencing side effects.

**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 to help you remember.**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 of this medicine.

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

You may need urgent medical attention.

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## While you are taking this medicine

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### **Things you must do**

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

If you plan to have surgery that needs a general anaesthetic or you are going into hospital, tell the doctor and pharmacist that you are taking roxithromycin.

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 roxithromycin has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical attention. Do not take any diarrhoea medicine without first checking with your doctor.

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

This may mean you have a fungal/yeast infection called thrush. Sometimes the use of roxithromycin

allows fungi/yeast to grow and the above symptoms to occur. Roxithromycin does not work 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 this medicine to treat any other complaints unless your doctor tells you to.

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

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

If you do not complete the full course prescribed by your doctor, all of 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 it may return.

### **Things to be careful of**

Be careful when driving or operating machinery until you know how this medicine affects you.

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

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## Side effects

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

This medicine helps to treat bacterial infections in most people, but it may have unwanted side effects in a few people. 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 if you notice any of the following:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore, itchy vagina and/or discharge
- nausea, vomiting, stomach pain, diarrhoea, flatulence, indigestion, reflux, loss of appetite
- red and/or itchy skin
- headache, dizziness, deafness/ringing in the ears
- confusion
- tiredness
- altered taste
- rash
- blurred vision and/or visual impairment

The above list includes some of the more common side effects of this medicine.

Tell your doctor as soon as possible if you notice any of the following, particularly if they occur several weeks after stopping treatment with roxithromycin:

- upper abdominal pain, which may radiate up to your back, nausea or vomiting (possible symptoms of pancreatitis)
- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may need urgent medical attention.

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

If any of the following happen, tell your doctor immediately or go to

## Accident and Emergency at your nearest hospital:

- hallucinations
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- signs of an allergic reaction, including swelling of the face, lips, mouth and tongue; difficulty in swallowing or breathing; itchy skin, rash, swelling,
- severe skin rash
- severe persistent diarrhoea
- progressive skin rash often with blisters or mucosal lesions (e.g. around the eyes, nose, mouth and genitals).

These are very serious side effects and you may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may occur in some patients.

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## Storage and disposal

### **Storage**

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

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

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

**Do not store your medicine 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.**

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## Product description

### **What APO-Roxithromycin looks like**

White to off-white round convex, film-coated tablets

### **Ingredients**

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

It also contains the following:

- maize starch
- hyprolosesilica - colloidal anhydrous
- sodium starch glycollate
- poloxamer
- povidone
- magnesium stearate
- talc - purified
- propylene glycol
- glucose
- titanium dioxide
- hypromellose.

This medicine is free from gluten, lactose, sucrose, tartrazine and other azo dyes.

### **Australian Registration Numbers**

APO-Roxithromycin 150 mg tablets (blister): AUST R 133748.

APO-Roxithromycin 300 mg tablets (blister): AUST R 133749.

\* Not all strengths, pack types and/or pack sizes may be available.

### **Sponsor**

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