

APO-Roxithromycin

Contains the active ingredient roxithromycin

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

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.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

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

It is used to treat:

- 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).

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.

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.

There is no evidence that this medicine is addictive.

Use in children

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

When you must not take it

Do not take this medicine if:

- You have severe liver problems.
- You are taking certain medicines for migraine headache called ergot alkaloids.
- You are hypersensitive to, or have had an allergic reaction to, roxithromycin or any other macrolide antibiotics (e.g. azithromycin, clarithromycin or erythromycin), or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, 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; fainting or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and

contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems (impaired function).
 - liver problems (hepatic cirrhosis with jaundice and/or ascites).
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines; this includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with roxithromycin. 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
- pimozide, an antipsychotic medicine
- rifabutin and bromocriptine (which use the CYP3A liver enzyme).

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with roxithromycin.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

Adults

The recommended adult dosage 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 dosage of roxithromycin given to children is dependent upon the child's weight.

The recommended dosage for children weighing 40 kg and over is 300 mg per day, taken according to the following dosage regimen:

- one 150 mg tablet in the morning and one 150 mg tablet in the evening.

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

How to take it

Swallow roxithromycin tablets whole with a glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember 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.

Make sure you have enough to last over weekends and holidays.

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 missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

If you get severe diarrhoea, tell your doctor immediately. Do this even if it

occurs several weeks after you have stopped 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. 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.

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.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor tells you to
- Stop taking your medicine, or change 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking roxithromycin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

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

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.

- 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 serious side effects. You may 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.

- Upper abdominal pain, which may radiate up to your back, nausea or vomiting (possible symptoms of pancreatitis).

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

- severe persistent diarrhoea
- progressive skin rash often with blisters or mucosal lesions (e.g. around the eyes, nose, mouth and genitals).

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

Allergic reactions

If you think you are having an allergic reaction to roxithromycin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it 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 this medicine 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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Roxithromycin 150mg looks like

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

Blister Pack of 10 tablets.

What APO-Roxithromycin 300mg looks like

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

Blister Pack of 5 tablets.

Ingredients

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

It also contains the following inactive ingredients:

- maize starch
- hydroxypropylcellulose
- silica - colloidal anhydrous
- sodium starch glycollate
- poloxamer
- povidone
- magnesium stearate
- talc - purified

- propylene glycol
- glucose
- titanium dioxide
- hypromellose.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of 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

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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