

APX-Roxithromycin

roxithromycin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APX-ROXITHROMYCIN.

It does not contain all of 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 APX-ROXITHROMYCIN against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

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

What APX-ROXITHROMYCIN is used for

APX-ROXITHROMYCIN is used to treat infections in different parts of the body caused by bacteria, such as:

- 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).

APX-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. APX-ROXITHROMYCIN, like other antibiotics, does not work against viral infections such as the flu.

Your doctor may have prescribed APX-ROXITHROMYCIN for another reason. Ask your doctor if you have any questions about why APX-ROXITHROMYCIN has been prescribed for you.

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

There is no evidence that APX-ROXITHROMYCIN is addictive.

Before you take it

When you must not take it

Do not take this medicine if you are allergic to:

- roxithromycin
- any other macrolide antibiotic eg, azithromycin, clarithromycin or erythromycin
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing or swelling.

Do not take APX-ROXITHROMYCIN if you have severe liver problems.

Do not take APX-ROXITHROMYCIN if you are taking certain medicines for migraine headache called ergot alkaloids (eg Cafergot, Ergodryl, Dihyergot).

Ask your doctor if you are not sure whether you are taking one of these medicines.

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

Do not take it if the expiry date (Exp.) printed on the pack has passed.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Your doctor will discuss the risks and benefits of using APX-ROXITHROMYCIN during pregnancy.

Tell your doctor if you are breast-feeding.

APX-ROXITHROMYCIN passes into the breast milk. Your doctor will discuss the risks and benefits of using this medicine while breast-feeding.

Tell your doctor if you have or have ever had any other medical conditions, including:

- kidney problems
- liver problems.

If you have not told your doctor about any of the above, tell him/her before you start taking APX-ROXITHROMYCIN.

Taking other medicines

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

Some medicines may be affected by APX-ROXITHROMYCIN, or may affect how well it works. These include:

- theophylline, a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine or dihydroergotamine
- 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 and/or irregular heart rhythms
- 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.

Your doctor can tell you what to do if you are taking any of these medicines.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking APX-ROXITHROMYCIN.

How to take it

How much to take

The recommended adult dosage is 300 mg per day which may be taken as 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 ask you to take a different dose.

The recommended dosage for children more than 40 kg, is one 150 mg tablet twice daily.

The dosage of APX-ROXITHROMYCIN given to children is dependant on the child's weight.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take APX-ROXITHROMYCIN

Swallow the tablets with a glass of water.

APX-ROXITHROMYCIN should be taken at least 15 minutes before food or on an empty stomach (i.e. more than 3 hours after a meal). The medicine works best if you take it on an empty stomach.

If you forget to take it

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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.

How long to take it

For treating infections, APX-ROXITHROMYCIN is usually taken for 5 to 10 days. However, your doctor may prescribe APX-ROXITHROMYCIN for longer periods. Check with your doctor if you are not sure how long you should be taking it.

Keep taking APX-ROXITHROMYCIN until you finish your pack or until your doctor recommends.

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

Your infection may not clear completely if you stop taking your medicine too soon.

If you take too much (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 APX-ROXITHROMYCIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

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

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking APX-ROXITHROMYCIN.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any

diarrhoea medicine without checking with your doctor.

If you get a sore, white mouth or tongue while taking or soon after stopping APX-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 this medicine allows fungi/yeast to grow and the above symptoms to occur. APX-ROXITHROMYCIN does not work against fungi/yeast.

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking APX-ROXITHROMYCIN.

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

Things you must not do

Do not stop taking your tablets because you are feeling better, unless advised by 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.

Do not use APX-ROXITHROMYCIN to treat any other conditions unless your doctor tells you to.

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

Side effects

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

Like all other medicines, 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.

Ask your doctor or pharmacist to answer any questions you may have.

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
- loss of appetite
- red and/or itchy skin
- headache, dizziness, ringing in the ears
- tiredness
- altered taste.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth and tongue
- severe persistent diarrhoea
- an allergic reaction (for example, itchy skin, rash, swelling, asthma)

These may be signs of a serious allergic reaction.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After finishing APX-ROXITHROMYCIN, tell your doctor immediately if you notice any of the following side effects:

- 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 have a serious

condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare. Do not take any diarrhoea medicine without first checking with your doctor.

Some people may get other side effects while taking APX-ROXITHROMYCIN.

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

You may not experience any of them.

After using it

Storage

Keep your 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.

Keep your tablets in a cool place where the temperature stays below 25°C and protect from light and moisture.

Do not store APX-ROXITHROMYCIN or any other medicine in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking this medicine, 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

APX-ROXITHROMYCIN comes in 2 strengths of tablets:

- APX-ROXITHROMYCIN 150mg- round white tablet. Each pack contains 10 tablets.

- APX-ROXITHROMYCIN
300mg- round white tablet. Each
pack contains 5 tablets.

Ingredients

The active ingredient in APX-
ROXITHROMYCIN is
roxithromycin.

- each APX-ROXITHROMYCIN
150mg tablet contains 150 mg
of roxithromycin
- each APX-ROXITHROMYCIN
300mg tablet contains 300 mg
of roxithromycin

The tablets also contain:

- low substituted hypolose
- collidal anhydrous silica
- purified talc
- povidone
- maize starch
- magnesium stearate
- hypromellose
- anhydrous glucose
- titanium dioxide
- propylene glycol.

The tablets do not contain gluten,
lactose, sucrose, tartrazine or any
other azo dyes.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Australian registration numbers:

APX-ROXITHROMYCIN 150mg-
AUST R 333544

APX-ROXITHROMYCIN 300mg-
AUST R 333543

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