

CONSUMER MEDICINE INFORMATION

ARROW - ROXITHROMYCIN

Roxithromycin 150 mg and 300 mg tablets

What is in this leaflet

This leaflet answers some common questions about ARROW - 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 ARROW - ROXITHROMYCIN 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 ARROW - ROXITHROMYCIN is used for

ARROW - ROXITHROMYCIN Tablets are 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).

ARROW - 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.

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

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

There is no evidence that ARROW - ROXITHROMYCIN Tablets is addictive.

ARROW - ROXITHROMYCIN is available only with a doctor's prescription.

Before you take ARROW - ROXITHROMYCIN

When you must not take it

Do not take ARROW - ROXITHROMYCIN if you are allergic to medicines containing roxithromycin, any other macrolides antibiotic eg, azithromycin, clarithromycin, erythromycin or 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 or other parts of the body
- rash, itching or hives on the skin.

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

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

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

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

Do not take ARROW - ROXITHROMYCIN 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 taking ARROW - ROXITHROMYCIN during pregnancy.

Tell your doctor if you are breastfeeding or intend to breastfeed.

ARROW - ROXITHROMYCIN passes into the breast milk. Your doctor will discuss the risks and benefits of taking ARROW - ROXITHROMYCIN while breastfeeding.

Tell your doctor if 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).

If you have not told your doctor about any of the above, tell him/her before you starting ARROW - 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 ARROW - 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, a medicine 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 ARROW - ROXITHROMYCIN.

How to take ARROW - ROXITHROMYCIN

How much to take

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

- 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 ARROW - 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 ARROW - ROXITHROMYCIN

Swallow the tablet whole with a glass of water.

When to take ARROW - ROXITHROMYCIN

ARROW - ROXITHROMYCIN should be taken at least 15 minutes before food or on an empty stomach (i.e. more than 3 hours after a meal). ARROW - ROXITHROMYCIN works best if you take it on an empty stomach. Food in the stomach can reduce the absorption of ARROW - ROXITHROMYCIN.

Take the tablet at about the same time of each day.

Taking your tablet at the same time each day will have the best effect on your infection. It will also help you to remember when to take it.

How long to take ARROW - ROXITHROMYCIN for

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

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

Do not stop taking ARROW - 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 forget to take ARROW - ROXITHROMYCIN

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.

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

If you take too much ARROW - ROXITHROMYCIN (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and

Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW - ROXITHROMYCIN Tablets.

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

Keep the telephone numbers for these places handy.

While you are taking ARROW - ROXITHROMYCIN

Things you must do

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

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

If you become pregnant while taking ARROW - ROXITHROMYCIN, tell your doctor immediately.

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 ARROW - 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 ARROW - 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 ARROW - ROXITHROMYCIN allows fungi/yeast to grow and the above symptoms to occur. ARROW - ROXITHROMYCIN does not work against fungi/yeast.

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 ARROW - ROXITHROMYCIN to treat any other conditions unless your doctor tells you to.

Do not give ARROW - ROXITHROMYCIN 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 ARROW - ROXITHROMYCIN.

Like other medicines, ARROW - ROXITHROMYCIN Tablets can cause some side effects. 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.

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 (eg. 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 ARROW - 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.

After taking ARROW - ROXITHROMYCIN

Storage

Keep ARROW - ROXITHROMYCIN 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 ARROW - ROXITHROMYCIN in a cool, dry place where the temperature stays below 25°C, and protect from light and moisture.

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

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

Do not store ARROW - ROXITHROMYCIN or other medicines in the bathroom or near a sink. Do not leave the tablets in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

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

Product description

What ARROW - ROXITHROMYCIN looks like

ARROW - ROXITHROMYCIN comes in 2 strengths of tablets:

- ARROW - ROXITHROMYCIN 150 - white, round film-coated tablets. Each pack contains 10 tablets
- ARROW - ROXITHROMYCIN 300 - white, round film-coated tablets. Each pack contains 5 tablets.

Ingredients

The active ingredient in ARROW - ROXITHROMYCIN is roxithromycin.

- each ARROW - ROXITHROMYCIN 150 tablet contains 150 mg of roxithromycin
- each ARROW - ROXITHROMYCIN 300 tablet contains 300 mg of roxithromycin.

The tablets also contain:

- low substituted hydroxypropyl cellulose (hyprolose)

- colloidal anhydrous silica
- purified talc
- povidone
- maize starch
- magnesium stearate
- hypromellose
- anhydrous glucose
- titanium dioxide
- propylene glycol.

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

Supplier

ARROW - ROXITHROMYCIN is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

Date of preparation

5 May 2017

(based on the data sheet dated 10 February 2017)