

# Roxithromycin-GA

roxithromycin film-coated tablets

## Consumer Medicine Information

### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Roxithromycin-GA.

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 risk of you taking this medicine against the benefits it is expected to have for you.

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

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

### WHAT ROXITHROMYCIN-GA IS USED FOR

This medicine is used to treat various infections 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).

It contains the active ingredient roxithromycin. Roxithromycin

belongs to a group of medicines called macrolides.

It works by killing or stopping the growth of the bacteria that are causing the infection. However, Roxithromycin-GA does not have any effect on 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 it for another reason.

This medicine is not addictive.

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

### BEFORE YOU TAKE ROXITHROMYCIN-GA

*When you must not take it*

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

- roxithromycin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other macrolide antibiotic (such as azithromycin, clarithromycin or erythromycin).

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 this medicine if you have severe problems with your liver.**

**Do not take this medicine if you are also taking certain medicines for migraine headache of the group of ergot alkaloids (such as Migral®, Cafergot®, Ergodryl®, Dihydroergot®).**

**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 any of the following medical conditions:**

- impaired kidney function
- problems with your liver (hepatic cirrhosis with jaundice and/or ascites).

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

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor or pharmacist if you plan to have surgery.**

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

*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-GA may interfere with each other.

These include:

- theophylline, a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine or dihydroergotamine
- disopyramide, a medicine used to treat irregular heart rhythms
- terfenadine and astemizole, medicines used to treat allergies
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- 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.

These medicines may be affected by Roxithromycin-GA, 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.

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## HOW TO TAKE ROXITHROMYCIN-GA

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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, ask your doctor or pharmacist for help.**

### *How much to take*

The recommended dosage for adults is 300mg per day. You may take this

according to one of the following dosage regimens:

- one 300mg tablet once a day, or
- one 150mg tablet twice a day, or
- two 150 mg tablets once a day.

The dose for a child will depend on this child's weight. The recommended dose for children weighing 40kg and more is 150mg twice a day. Roxithromycin-GA should not be used for children less than 40kg in weight.

No dose adjustment is required for the use in the elderly.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Roxithromycin-GA may not work as well and your problem may not improve.

### *How to take it*

Roxithromycin-GA tablets should be swallowed whole with a glass of water.

If you need to break Roxithromycin-GA, hold the tablet with both hands and snap along the break line.



### *When to take Roxithromycin-GA*

**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.

**Take your medicine on an empty stomach, for example, at least 15 minutes before food or at least 3 hours after food.**

Food can interfere with the absorption of this medicine.

### *How long to take Roxithromycin-GA*

Roxithromycin-GA is usually taken for 5 to 10 days for treating infections. Your doctor may want you to take Roxithromycin-GA for a longer period.

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

It is important to keep taking your medicine even if you feel well.

### *If you forget to take it*

**Take your dose as soon as you remember, and continue to take it as you would normally.**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

This may increase the chance of you getting an unwanted side effect.

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.

### *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 Roxithromycin-GA. 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 ROXITHROMYCIN-GA

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### *Things you must do*

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

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

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

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

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

**Tell your doctor immediately if you get severe diarrhoea. Do this even if it occurs several weeks after Roxithromycin-GA has been stopped.**

Diarrhoea may be a sign for a serious condition affecting your bowel. You may need urgent medical attention. Check with your doctor before taking any diarrhoea medication.

**Tell your doctor or pharmacist if you get vaginal itching or discharge. Tell your doctor or pharmacist if you get a sore, white mouth or tongue while or shortly after taking Roxithromycin-GA.**

These could be the symptoms of a fungal/yeast infection called thrush. The use of Roxithromycin-GA can allow fungi/yeast to grow and cause the above symptoms. Roxithromycin-GA is not effective 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 more than the recommended dose unless your doctor or pharmacist tells you to.**

**Do not take Roxithromycin-GA to treat any other complaints unless your doctor tells you to.**

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

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

If you stop taking Roxithromycin-GA too early, not all of the bacteria might be killed. The remaining could start to grow again and prevent your infection from clearing completely or even cause it to return.

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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-GA.**

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 or pharmacist if you notice any of the following and they worry you:**

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

These are mild side effects of the medicine, and are shortlived.

**Tell your doctor as soon as possible if you notice any of the following, in particular if they occur several weeks after you finished taking Roxithromycin-GA:**

- severe abdominal or stomach cramps

- watery and severe diarrhoea, which may even be bloody
- fever, in combination with one or both of the above.

The above list includes serious side effects of Roxithromycin-GA. You may suffer from a serious condition affecting your bowel requiring medical attention. **Check with your doctor before taking any diarrhoea medication.**

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- an allergic reaction. 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.
- severe persistent diarrhoea.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

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## AFTER TAKING ROXITHROMYCIN-GA

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### *Storage*

**Keep your medicine in the original container.**

If you take it out of its original container it may not keep well.

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

**Do not store Roxithromycin-GA 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

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*What it looks like*

Roxithromycin-GA comes in two types of tablets:

Roxithromycin-GA 150mg - white, round, convex film-coated tablets, scored on one side, embossment R150 on the other side.

Available in blister packs of 10 tablets.

Roxithromycin-GA 300mg - white, round, convex film-coated tablets, scored on one side, embossment R300 on the other side.

Available in blister packs of 5 tablets.

*Ingredients*

Active ingredient:

- Roxithromycin-GA 150mg - 150mg roxithromycin
- Roxithromycin-GA 300mg - 300mg roxithromycin

Inactive ingredients:

- microcrystalline cellulose
- povidone K30
- croscarmellose sodium
- precipitated silica
- lactose
- hypromellose
- titanium dioxide
- magnesium stearate
- macrogol 4000
- poloxamer 188.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

*Supplier*

Amneal Pharma Australia  
Pty Ltd  
12 River Street  
South Yarra VIC 3141  
Australia

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**Australian Register Numbers:**

Roxithromycin-GA 150mg film-coated tablets: AUST R 154656

Roxithromycin-GA 300mg film-coated tablets: AUST R 154657