

# ROXIMYCIN®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using ROXIMYCIN?

ROXIMYCIN contains the active ingredient roxithromycin. ROXIMYCIN is used to treat infections in different parts of the body caused by bacteria. For more information, see Section [1. Why am I using ROXIMYCIN?](#) in the full CMI.

### 2. What should I know before I use ROXIMYCIN?

Do not use if you have ever had an allergic reaction to roxithromycin or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use ROXIMYCIN?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ROXIMYCIN and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ROXIMYCIN?

The recommended adult dosage is 300 mg per day. The recommended dosage for children more than 40 kg is one 150 mg tablet twice daily. More instructions can be found in Section [4. How do I use ROXIMYCIN?](#) in the full CMI.

### 5. What should I know while using ROXIMYCIN?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or dentist you visit that you are using ROXIMYCIN.</li><li>• If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.</li><li>• If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after ROXIMYCIN has been stopped.</li><li>• If you get a sore, white mouth or tongue while taking, or soon after stopping ROXIMYCIN, tell your doctor or pharmacist.</li><li>• Tell your doctor or pharmacist if you get vaginal itching or discharge.</li><li>• If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking ROXIMYCIN.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take more than the recommended dose unless your doctor or pharmacist tells you to.</li><li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li><li>• Do not use this medicine to treat any other complaints unless your doctor tells you to.</li><li>• Do not stop taking your tablets because you are feeling better, unless advised by your doctor or pharmacist.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Make sure you know how ROXIMYCIN affects you before driving or operating machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep the medicine in a cool dry place where the temperature stays below 25°C.</li><li>• Keep the tablets in the blister until it's time to take them.</li></ul>

For more information, see Section [5. What should I know while using ROXIMYCIN?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include: rash; loss of appetite. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ROXIMYCIN®

Active ingredient: *roxithromycin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ROXIMYCIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ROXIMYCIN.**

**Where to find information in this leaflet:**

- [1. Why am I using ROXIMYCIN?](#)
- [2. What should I know before I use ROXIMYCIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ROXIMYCIN?](#)
- [5. What should I know while using ROXIMYCIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ROXIMYCIN?

**ROXIMYCIN contains the active ingredient roxithromycin.** ROXIMYCIN 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.

ROXIMYCIN, like other antibiotics, does not work against viral infections such as the flu.

ROXIMYCIN is used to treat infections in different parts of the body caused by bacteria. For example:

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

## 2. What should I know before I use ROXIMYCIN?

### Warnings

**Do not use ROXIMYCIN if:**

- you are allergic to roxithromycin, or any other macrolide antibiotic e.g. azithromycin, clarithromycin or 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.

Always check the ingredients to make sure you can use this medicine.

- you have severe liver problems

- you are taking certain medicines for migraine headache called ergot alkaloids. Ask your doctor if you are not sure if you are taking one of these medicines.
- the packaging is torn or shows signs of tampering
- the expiry date (EXP) on the pack has passed.

**Check with your doctor if you:**

- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- are pregnant or intend to become pregnant
- are breast-feeding or plan to breast-feed
- 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)
  - congenital prolongation of the QT interval, with ongoing proarrhythmic heart conditions
- have any other medical conditions
- take any medicines for any other condition
- plan to have surgery

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. Like most medicines of this kind, ROXIMYCIN is not recommended for use during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed. ROXIMYCIN passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

### Use in Elderly

ROXIMYCIN can be used in the elderly with no dosage adjustment required.

## 3. What if I am taking other medicines?

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

There may be interference between ROXIMYCIN and some other medicines, including:

- theophylline (Nuelin), a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine or dihydroergotamine
- disopyramide (Rythmodan), a medicine to treat irregular heart rhythms
- terfenadine and astemizole, over the counter medicines used to treat allergies
- warfarin (Coumadin, Marevan), a medicine used to prevent blood clots
- digoxin (Lanoxin), a medicine used to treat heart failure

- midazolam (Hypnovel), used to induce sleep before operations
- ciclosporin (Neoral, Sandimmun), a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- cisapride, a medicine used to treat stomach reflux
- pimozide (Orap), an antipsychotic medicine
- hydroxychloroquine or chloroquine, used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria. Taking these medicines at the same time as ROXIMYCIN may increase the chance of you getting side effects that affect your heart.

These medicines may be affected by ROXIMYCIN, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ROXIMYCIN.**

## 4. How do I use ROXIMYCIN?

### How much to take

- The recommended adult dose is 300 mg per day which may be taken according to one of the following alternative 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 dose for children will depend on the child's weight.
- Your doctor will tell you how much ROXIMYCIN your child should take.
- Follow the instructions provided and use ROXIMYCIN until your doctor tells you to stop.

### When to take ROXIMYCIN

- Take ROXIMYCIN at least 15 minutes before food or on an empty stomach (i.e. more than 3 hours after a meal).
- ROXIMYCIN works best if you take it on an empty stomach. Food in the stomach can reduce the absorption of ROXIMYCIN.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### How to take ROXIMYCIN

- Swallow the tablet whole with a glass of water.

### How long to take it

- For treating infections, ROXIMYCIN is usually taken for 5 to 10 days. However your doctor may prescribe it for longer periods.
- Continue taking the tablets until you finish the pack or until your doctor or pharmacist tells you to stop
- Do not stop taking ROXIMYCIN, even if you feel better after a few days, unless advised by your doctor.
- If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

### If you forget to use ROXIMYCIN

ROXIMYCIN should be used regularly at the same time each day.

**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 it 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 use too much ROXIMYCIN

If you think that you have used too much ROXIMYCIN, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using ROXIMYCIN?

### Things you should do

- 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, pharmacist or nurse immediately. Do this even if it occurs several weeks after ROXIMYCIN has been stopped. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any anti-diarrhoea medicine without first checking with your doctor.
- If you get a sore, white mouth or tongue while taking, or soon after stopping ROXIMYCIN, tell your doctor or pharmacist. Also tell your doctor or pharmacist if you get vaginal itching or discharge. This may mean you have a fungal/yeast infection called thrush. Sometimes the use of ROXIMYCIN allows fungi/yeast to grow and the above symptoms to occur. ROXIMYCIN does not work against fungi/yeast.
- Tell all the doctors, dentists and pharmacists who are treating you that you are taking ROXIMYCIN.
- Visit your doctor regularly so they can check on your progress.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking ROXIMYCIN.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

### Call your doctor straight away if you:

- become pregnant while taking ROXIMYCIN.

Remind any doctor, dentist or pharmacist you visit that you are using ROXIMYCIN.

### Things you should not do

- Do not take more than the recommended dose unless your doctor or pharmacist tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking your tablets or lower the dose because you are feeling better, unless advised by your doctor or pharmacist.

If you do not complete the full course prescribed by your doctor, all 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.

### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how ROXIMYCIN affects you.

ROXIMYCIN may cause dizziness in some people. If you experience any dizziness, do not drive, operate machinery or do anything else that could be dangerous.

### Drinking alcohol

#### Tell your doctor if you drink alcohol.

### Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

#### Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• oral thrush - white, furry, sore tongue and mouth</li> <li>• vaginal thrush - sore and itchy vagina and/or discharge</li> <li>• nausea, vomiting, stomach pain, diarrhoea, flatulence</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• pancreatitis - an inflammation of the pancreas</li> <li>• loss of appetite</li> <li>• red and/or itchy skin</li> <li>• hallucinations</li> <li>• confusion</li> <li>• headache, dizziness, ringing in the ears, temporary deafness</li> <li>• vertigo</li> <li>• tiredness</li> <li>• altered taste</li> <li>• rash</li> <li>• blurred vision and/or visual impairment</li> </ul>	<p><b>These side effects are usually mild and short-lived.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• severe abdominal cramps or stomach cramps</li> <li>• severe, persistent diarrhoea, which may be watery or bloody</li> <li>• fever, in combination with one or both of the above</li> </ul>	<p><b>Tell your doctor or pharmacist immediately if you notice any of these side effects, particularly if they occur several weeks after stopping treatment with ROXIMYCIN.</b></p> <p><b>These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention.</b></p> <p><b>Do not take any diarrhoea medicine without first checking with your doctor.</b></p>
<ul style="list-style-type: none"> <li>• frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>• severe persistent diarrhoea</li> <li>• swelling of the face, lips, mouth and tongue</li> <li>• difficulty in swallowing and breathing</li> <li>• an allergic reaction (for example, itchy skin, rash, swelling, asthma)</li> </ul>	<p><b>Stop taking this medicine and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• severe blisters and bleeding in the lips, mouth, nose and genitals</li> <li>• severe skin rash</li> </ul>	<p><b>notice any of these serious side effects. These are very serious side effects. If you have them, you may have had a serious allergic reaction to ROXIMYCIN. You may need urgent medical attention or hospitalisation.</b></p>

the other. Each blister pack contains 5 tablets (AUST R 99939).

#### Who distributes ROXIMYCIN

#### Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

#### What ROXIMYCIN contains

<b>Active ingredient (main ingredient)</b>	Each tablet contains either 150 mg or 300 mg of roxithromycin
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• povidone</li> <li>• hypolose</li> <li>• maize starch</li> <li>• poloxamer</li> <li>• colloidal anhydrous silica</li> <li>• purified talc</li> <li>• magnesium stearate</li> <li>• glucose</li> <li>• OPADRY complete film coating system OY-S-58918 White (AUST PI No.: 10050).</li> </ul>
<b>Potential allergens</b>	Trace quantities of sulfites

**Do not take this medicine if you are allergic to any of these ingredients.**

#### What ROXIMYCIN looks like

ROXIMYCIN tablets come in 2 strengths:

- ROXIMYCIN 150 mg - white, round, film coated, normal convex tablets, marked "150" "R" on one side and "G" on the other. Each blister pack contains 10 tablets (AUST R 99937).
- ROXIMYCIN 300 mg - white, round, film coated, normal convex tablets, marked "300" "R" on one side and "G" on the other.