ROXITHROMYCIN-WGR Tablets

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 ROXITHROMYCIN-WGR?

ROXITHROMYCIN-WGR contains the active ingredient roxithromycin. ROXITHROMYCIN-WGR is used to treat infections in different parts of the body caused by bacteria. For more information, see Section 1. Why am I using ROXITHROMYCIN-WGR? in the full CMI.

2. What should I know before I use ROXITHROMYCIN-WGR?

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 ROXITHROMYCIN-WGR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ROXITHROMYCIN-WGR 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 ROXITHROMYCIN-WGR?

- 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 ROXITHROMYCIN-WGR? in the full CMI.

5. What should I know while using ROXITHROMYCIN-WGR?

Things you should do	• Remind any doctor or dentist you visit that you are using ROXITHROMYCIN-WGR. • 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 ROXITHROMYCIN-WGR has been stopped. • If you get a sore, white mouth or tongue while taking, or soon after stopping ROXITHROMYCIN-WGR, tell your doctor or pharmacist. • Tell your doctor or pharmacist if you get vaginal itching or discharge. • If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking ROXITHROMYCIN-WGR.
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 because you are feeling better, unless advised by your doctor or pharmacist.
Driving or using machines	• Make sure you know how ROXITHROMYCIN-WGR affects you before driving or operating machinery.
Drinking alcohol	• Tell your doctor if you drink alcohol
Looking after your medicine	• Keep the medicine in a cool dry place where the temperature stays below 25°C. • Keep the tablets in the blister until it is time to take them

For more information, see Section 5. What should I know while using ROXITHROMYCIN-WGR? in the full CMI.

6. Are there any side effects?

Common side effects include: rash; loss of appetite. Refer to the CMI for all side effects.

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.

ROXITHROMYCIN-WGR TABLETS

Active ingredient(s): *Roxithromycin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ROXITHROMYCIN-WGR. **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 ROXITHROMYCIN-WGR**.

Where to find information in this leaflet:

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

1. Why am I using ROXITHROMYCIN-WGR?

ROXITHROMYCIN-WGR contains the active ingredient roxithromycin. ROXITHROMYCIN-WGR 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-WGR, like other antibiotics, does not work against viral infections such as the flu.

ROXITHROMYCIN-WGR 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 ROXITHROMYCIN-WGR?

Warnings

Do not use ROXITHROMYCIN-WGR if:

- you are allergic to roxithromycin, or any other macrolide antibiotic e.g. 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, shortness of breath or swelling of the face, lips or tongue which cause difficulty in swallowing or breathing. Always check the ingredients to make sure you can use this medicine.
- you have severe liver problems
- if you are taking certain medicines migraine headache called ergot alkaloids e.g. Cafergot, Dihydergot; (not all brands listed
- the product has expired or the packaging appears tampered with.

Check with your doctor or pharmacist if you:

- have allergies to any other substances, such as foods, preservatives or dyes
- are pregnant or intend to become pregnant
- are breastfeeding or plan to breastfeed
- have or have had the following medical conditions:
  - kidney problems (impaired function)
  - liver problems (hepatic cirrhosis with jaundice and /or ascites)
- 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, ROXITHROMYCIN-WGR 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. ROXITHROMYCIN-WGR 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 the Elderly

ROXITHROMYCIN-WGR 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. Some medicines may be affected by ROXITHROMYCIN-WGR, or

may affect how well ROXITHROMYCIN-WGR works. These include:

- theophylline (Neulin), a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine (Cafergot)or dihydroergotamine (Dihydergot tablets)
- disopyramide, 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, Sigmaxin), a medicine used to treat heart failure
- midazolam (Hypnovel, Midazolam Sandoz), used to induce sleep before operations
- ciclosporin (Neoral, Cicoral, Cysporin, Sandimmun), 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 (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 ROXITHROMYCIN-WGR may increase the chance of you getting side effects that affect your heart.

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

4. How do I use ROXITHROMYCIN-WGR?

How much to take

- The recommended adult dosage 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 dosage of ROXITHROMYCIN-WGR given to children is dependent on the child's weight.
- Your doctor will tell you exactly how much to take.
- Follow the instructions provided and use ROXITHROMYCIN-WGR until your doctor tells you to stop.

When to take / use ROXITHROMYCIN-WGR

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

How to take ROXITHROMYCIN-WGR?

- Swallow the tablets whole with a glass of water.

How long to take it

- For treating infections, ROXITHROMYCIN-WGR is usually taken for 5 to 10 days. However, your doctor may prescribe ROXITHROMYCIN-WGR for longer periods.
- Continue taking the tablets until you finish the pack or until your doctor or pharmacist tells you to stop.

If you forget to use ROXITHROMYCIN-WGR

ROXITHROMYCIN-WGR 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.

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

If you use too much ROXITHROMYCIN-WGR

If you think that you have used too much ROXITHROMYCIN-WGR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 ROXITHROMYCIN-WGR?

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 ROXITHROMYCIN-WGR 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 diarrhoea medicine without first checking with your doctor.
- If you get a sore, white mouth or tongue while taking, or soon after stopping ROXITHROMYCIN-WGR, 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 ROXITHROMYCIN-WGR allows fungi/yeast to grow and the above symptoms to occur. ROXITHROMYCIN-WGR does not work against fungi/yeast.

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking ROXITHROMYCIN-WGR.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking ROXITHROMYCIN-WGR.
- 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:

- If you become pregnant while you are taking ROXITHROMYCIN-WGR, tell your doctor or pharmacist immediately.

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 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 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ROXITHROMYCIN-WGR affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Do not use this medicine after the expiry date.

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.

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.

Less serious side effects

Less serious side effects	What to do
• oral thrush - white, furry, sore tongue and mouth • vaginal thrush - sore and itchy vagina and/or discharge • nausea, vomiting, stomach pain, indigestion, diarrhoea, flatulence • loss of appetite • red and/or itchy skin • headache, dizziness, ringing in the ears • hallucinations • confusion • tiredness • altered taste • rash • blurred vision and/or visual impairment	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **These side effects are usually mild and short-lived.**

Serious side effects

Serious side effects	What to do
• severe abdominal cramps or stomach cramps • watery and severe diarrhoea, which may sometimes be bloody • fever, in combination with one or both of the above	**Tell your doctor or pharmacist immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with ROXITHROMYCIN-WGR.** **These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention Do not take any diarrhoea medicine without**

	first checking with your doctor
• frequent infections such as fever, severe chills, sore throat or mouth ulcers • severe persistent diarrhoea • swelling of the face, lips, mouth and tongue • difficulty in swallowing or breathing • an allergic reaction (for example, itchy skin, rash, swelling, asthma) • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals • severe skin rash.	**Stop taking this medicine and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you 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 ROXITHROMYCIN-WGR. You may need urgent medical attention or hospitalisation**

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. 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 available with a doctor's prescription.

What ROXITHROMYCIN-WGR contains

Active ingredient (main ingredient)	Each tablet contains either 150 mg or 300 mg of roxithromycin
Other ingredients (inactive ingredients)	ROXITHROMYCIN-WGR **tablets**: • hyprolose • colloidal anhydrous silica • purified talc • povidone • maize starch • magnesium stearate • hypromellose • anhydrous glucose • titanium dioxide • propylene glycol.

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

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

What ROXITHROMYCIN-WGR looks like

ROXITHROMYCIN-WGR comes in 2 strengths of tablets:

- ROXITHROMYCIN-WGR 150- round white tablet. Each pack contains 10 tablets (AUST R 333546).
- ROXITHROMYCIN-WGR 300- round white tablet. Each pack contains 5 tablets (AUST R 333545).

Who distributes ROXITHROMYCIN-WGR

Wagner Pharmaceuticals Pty Ltd

6 Albert Street

Preston VIC 3121

Tel: 1800 936 140

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