RIMYCIN®

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 taking RIMYCIN?

RIMYCIN contains the active ingredient rifampicin. RIMYCIN is an antibiotic taken with other medicines to treat tuberculosis, leprosy and mycobacterium ulcerans (Buruli ulcer). It is also taken to prevent meningococcal disease and infections caused by *Haemophilus Influenza* Type B. For more information, see Section 1. Why am I taking RIMYCIN? in the full CMI.

2. What should I know before I take RIMYCIN?

Do not take RIMYCIN if you have ever had an allergic reaction to RIMYCIN or any of the ingredients listed at the end of the CMI.
Do not take RIMYCIN if you have jaundice.
Do not take RIMYCIN if you are taking saquinavir, ritonavir, cabotegravir, fostemsavir or lenacapavir. These are medicines used to treat AIDS and HIV.

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 or planning to breastfeed.
For more information, see Section 2. What should I know before I take RIMYCIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RIMYCIN 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 take RIMYCIN?

Follow the instructions provided when RIMYCIN was prescribed, including the number of days it should be taken.

More instructions can be found in Section 4. How do I take RIMYCIN? in the full CMI.

5. What should I know while taking RIMYCIN?

Things you should do	• Remind any doctor, dentist, surgeon, or pharmacist you visit that you are taking RIMYCIN.

	• You should see your doctor monthly for a check-up. • Continue taking RIMYCIN exactly as prescribed by your doctor. • If you have a blood or urine test, tell your doctor you are taking RIMYCIN. • If you are about to be started on a new medicine, including oral contraceptives, tell your doctor you are taking RIMYCIN.
Things you should not do	• Do not stop taking this medicine because you feel better.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how RIMYCIN affects you.
Looking after your medicine	• Store below 25°C. • Store RIMYCIN in a cool dry place away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while taking RIMYCIN? in the full CMI.

6. Are there any side effects?

Serious side effects include allergic reactions, interstitial lung disease (including pneumonitis), severe bleeding or bruising, severe diarrhoea, severe stomach cramps, worsening of tuberculosis symptoms typically associated with exaggerated inflammatory symptoms including fever, swollen lymph nodes, breathlessness, cough and other symptoms such as headache, loss of appetite and weight loss. Stop using RIMYCIN and immediately contact a doctor if you experience any of the following symptoms such as nausea or vomiting, fever, feeling tired, loss of appetite, dark-colored urine, light-colored faeces, yellowing of the skin or white part of the eyes, itching, rash or upper stomach pain. These symptoms may be signs of liver injury.
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.

RIMYCIN®

Active ingredient(s): *rifampicin*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking RIMYCIN?

RIMYCIN contains the active ingredient rifampicin. RIMYCIN is an antibiotic which kills certain types of bacteria that can cause serious infections.

RIMYCIN is taken with other medicines to treat tuberculosis and is taken to treat leprosy. RIMYCIN is used to treat mycobacterium ulcerans (Buruli

ulcer) in combination with other antibiotics. RIMYCIN is also taken to prevent the following diseases:

- **Meningococcal disease that can cause meningitis.**
- **Infections caused by the bacteria,** *Haemophilus Influenzae* **Type B. Despite the name, it is not related to influenza ('the flu'). Symptoms of this infection can include meningitis, pneumonia, or conjunctivitis.**

2. What should I know before I take RIMYCIN?

Warnings

Do not take RIMYCIN if:

- you are allergic to rifampicin or other similar antibiotics such as rifabutin or rifaximin.
- you are allergic to any of the ingredients listed at the end of this leaflet.

  Always check the ingredients to make sure you can take this medicine.
- you are taking saquinavir/ritonavir. These medicines are used to treat acquired immune deficiency syndrome (AIDS) and human immunodeficiency virus (HIV) infections.
- you have jaundice (yellowing of the eyes and skin)

- you are taking medicine called lurasidone (medicine for schizophrenia and bipolar disorder), as rifampicin may reduce blood levels of lurasidone.
- you are taking cabotegravir, fostemsavir and lenacapavir for viral infections like HIV as rifampicin may reduce the blood levels of these medicines.
- you are breastfeeding or planning to breastfeed.
- you have previously taken any rifampicin containing medicinal product and had liver problems. If you are unsure talk to your doctor.

  Inflammation of the liver has been reported in patients taking RIMYCIN with symptoms developing within a few days to a few months following the start of treatment. Stop using RIMYCIN and contact a doctor if you have symptoms of liver problems (see Section 6. Are there any side effects?)

Check with your doctor if you:

- have any other medical conditions
- have any problems with your liver including liver disease
- have a problem with bleeding or a tendency to bruise easily
- have diabetes
- are taking other antibiotics
- wear soft contact lenses.
- Urine, faeces, saliva, sputum, sweat, tears and teeth may be coloured red-orange, yellow or brown by RIMYCIN. Soft contact lenses may be permanently stained.

- are taking any medicines for any other condition
- are taking oral contraceptives. You should change to an alternative method of birth control.
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- have a history of lung inflammation (interstitial lung disease/pneumonitis)
- if you experience reappearance or worsening of symptoms of tuberculosis (see Section 6. Are there any side effects)
- develop a rash or experience any symptoms of thrombotic microangiopathy during your treatment (see Section 6. Are there any side effects?)

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

Check with your doctor if you are pregnant or intend to become pregnant.

RIMYCIN should not be used while breastfeeding. RIMYCIN passes into breast milk and there is a possibility your baby may be affected.

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 interfere with RIMYCIN and affect how it works.

RIMYCIN should not be taken with the following medicines:

- the combination of saquinavir and ritonavir, antiviral agents used to treat acquired immune deficiency syndrome (AIDS) and human immunodeficiency virus (HIV) infections.
- medicines used to treat viral infections, such ascabotegravir, fostemsavir and lenacapavir
- If you are taking dapsone (an antibiotic) with rifampicin, it may cause methemoglobinemia (decrease in oxygen in your blood caused by changes in red blood cells).
- If you are taking paracetamol and rifampicin, it can increase the risk of liver damage.
- halothane, a general anaesthetic (a sleep inducing medicine)
- medicines used to treat Hepatitis C (antiviral agents), such as daclatasvir, simeprevir, sofosbuvir and telaprevir
- Cephalosporin antibiotics, such as cefazolin used to treat infection

- oral contraceptives

RIMYCIN and some medicines may interfere with each other and affect how they work, such as:

- antacids
- atovaquone
- isoniazid
- p-aminosalicylic acid (PAS)
- mifepristone
- medicines for the treatment or prevention of breast cancer
- medicines used to treat thyroid deficiency
- medicines for nocturnal cramps
- medicines for breathing difficulties
- medicines to treat diabetes
- medicines to treat nausea or vomiting

Heart or blood-related

- medicines that thin the blood, such as clopidogrel
- medicines to lower cholesterol
- medicines for treating heart problems
- medicines for treating high blood pressure, such as enalapril

Infections or immune system-related

- medicines to treat bacterial infections such as antibiotics
- medicines to treat fungal infections, such as caspofungin, fluconazole, itraconazole or ketoconazole
- medicines to treat tuberculosis or leprosy

- medicines for treating human immunodeficiency virus (HIV)
- medicines to treat malaria
- medicines to treat inflammatory conditions
- medicines used to keep the body from rejecting transplanted organs

Mental health, brain or pain-related

- medicines to treat mental illnesses, such as anxiety, depression, schizophrenia, or bipolar disorder
- medicines used to control or prevent seizures
- medicines that can cause sedation
- medicines for pain

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

4. How do I take RIMYCIN?

How much to take

- Follow the instructions provided when RIMYCIN was prescribed, including the number of days it should be taken.
- Swallow RIMYCIN capsules whole with a glass of water.
- If you need to take an antacid, take it at least 1 hour after your dose of RIMYCIN.

When to take RIMYCIN

- RIMYCIN capsules should be taken on an empty stomach at least 30 minutes before or 2 hours after a meal.

If you forget to take RIMYCIN

RIMYCIN should be taken regularly at the same time each day. If you miss your dose at the usual time, take the dose as soon as you remember, and then resume taking RIMYCIN as directed.

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 are unsure about taking the next dose, speak to your doctor or pharmacist.

If you take too much RIMYCIN

If you think that you have used too much RIMYCIN, 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.

- If you take too much RIMYCIN you may experience nausea, vomiting, stomach pain, itching, headache, tiredness, dizziness, swelling, fast or uneven heartbeat or other problems with heartbeating.

5. What should I know while taking RIMYCIN?

Things you should do

- You should see your doctor monthly for a check-up. Your doctor may order blood tests from time-to-time. to check your progress or check for any side effects.
- Continue taking RIMYCIN exactly as prescribed by your doctor.
- If you have a blood test or urine test, tell your doctor you are taking RIMYCIN. RIMYCIN may affect the results of some blood and urine tests.
- If you are about to be started on a new medicine, including oral contraceptives, tell your doctor that you are taking RIMYCIN.
- If you are using oral contraception you should change to alternative methods of birth control.

Call your doctor straight away if you:

- develop new or sudden worsening of shortness of breath, possibly with a dry cough or fever that is not responding to antibiotic treatment

  These could be symptoms of lung inflammation (interstitial lung disease/pneumonitis) and can lead to serious breathing problems due to collection of fluid in the lungs and interfere with normal breathing which can lead to life threatening conditions.

- become or intend to become pregnant
- are breastfeeding or intend to breastfeed
- are about to start taking any new medicine

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

Things you should not do

- Do not stop taking this medicine because you feel better. If you do not complete the full treatment your infection may not completely clear or may return.

Driving or using machines

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

RIMYCIN may cause dizziness, drowsiness or other undesirable effects in some people.

Looking after your medicine

- Store below 25°C

Follow the instructions in the packaging 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
Central nervous system-related: • drowsiness • fatigue • difficulty in concentrating • confusion • mental problems. **General:** • problems with your period • urine, faeces, saliva, sputum, sweat, tears and teeth may be coloured red-orange, yellow or brown by RIMYCIN. Soft contact lenses may be permanently stained. **Skin or eye-related:** • yellow discolouration of skin or eyes • conjunctivitis • problems with your eyesight.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
Thrush-related: • white, furry, sore tongue and mouth. These are signs of oral thrush • sore and itchy vagina with or without discharge. These are signs of vaginal thrush. **Muscle or nerve-related:** • poor coordination • muscle weakness • pain in the fingers or toes • numbness. **Stomach or gut-related:** • heartburn • loss of appetite • nausea • vomiting • upset stomach • gut discomfort • wind • cramps • diarrhoea. Do not take any diarrhoea medicine	

Less serious side effects	What to do
without first checking with your doctor. **Blood related:** • high blood levels of uric acid.	

Serious side effects

Serious side effects	What to do
Liver-related: • nausea or vomiting, fever, feeling tired, loss of appetite, dark-colored urine, light-colored faeces, yellowing of the skin or white part of the eyes, itching, rash or upper stomach pain.	**Stop using RIMYCIN and immediately contact a doctor if you experience any of these symptoms. These symptoms may be signs of liver injury.**
Skin-related: • severe red and/or itchy skin, blisters or pimples, bleeding, peeling or bruising of the skin. **Blood and lymph related:**	**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.**

Serious side effects	What to do
• blood in the urine or any other urination disturbances • severe bleeding or bruising more easily than normal • blood clots in small blood vessels (thrombotic microangiopathy). Symptoms may include increased bruising, bleeding, fever, extreme weakness, headache, dizziness or light-headedness. Your doctor may find changes in your blood and the function of your kidneys. **General** • itching, weakness, loss of appetite, nausea, vomiting, stomach or gut pain, yellowing of the eyes or skin or dark urine • worsening of tuberculosis symptoms which are typically associated with	

Serious side effects	What to do
exaggerated inflammatory symptoms (reported between 2 weeks and as late as 18 months after the initiation of anti-tuberculosis treatment). These symptoms include fever, swollen lymph nodes, breathlessness and cough. Other symptoms include headache and gut symptoms such as loss of appetite and weight loss • fever, chills, headache or dizziness • bone pain • new or sudden worsening of shortness of breath, possibly with a cough or fever (interstitial lung disease/ pneumonitis). **Liver-related:** • inflammation of the liver as shown by yellowing of the skin and white part of eyes. This may	

Serious side effects	What to do
be associated with an increase in liver enzymes as shown through a blood test. **Allergy-related:** • swelling of the face, lips, tongue or throat which may cause difficulty in breathing or swallowing.	
Stomach or gut-related: • severe stomach cramps or gut cramps • watery and severe diarrhoea, which may also be bloody. Do not take any diarrhoea medicine without first checking with your doctor • fever, in combination with one or both above.	**Tell your doctor immediately if you notice any of these serious side effects, particularly if they occur several weeks after stopping treatment with RIMYCIN.** **These are rare but serious side effects. You may have a rare serious condition affecting your bowel, which may need urgent medical attention.**

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 only available with a doctor's prescription.

What RIMYCIN contains

Active ingredient **(main ingredient)**	150 mg or 300 mg of rifampicin per capsule
Other ingredients **(inactive ingredients)**	• ascorbic acid • brilliant blue FCF • colloidal anhydrous silica • erythrosine • gelatin • lactose monohydrate

	• magnesium stearate • purified talc • purified water • sodium lauryl sulfate • titanium dioxide RIMYCIN 150 capsules also contain: • iron oxide red • iron oxide yellow
Potential allergens	Lactose and sulfites.

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

What RIMYCIN looks like

RIMYCIN 150 mg capsule is a size 3 hard gelatin capsule, maroon body with black cap (AUST R 48230).

RIMYCIN 300 mg capsules is a size 1 hard gelatin capsule with maroon body and cap (AUST R 48231).

RIMYCIN comes in bottles of 10 and 100 capsules.

Who distributes RIMYCIN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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RIMYCIN® is a Viatris company trade mark

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