Rifadin® Injection

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 being given Rifadin?

Rifadin contains the active ingredient rifampicin. Rifadin is an antibiotic taken with other medicines to treat tuberculosis and is taken to treat leprosy. 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 being given Rifadin? in the full CMI.

2. What should I know before I am given Rifadin?

Do not take Rifadin if you have ever had an allergic reaction to Rifadin or any of the ingredients listed at the end of the CMI.

Do not take Rifadin if you have jaundice.

Do not take Rifadin if you are taking saquinavir, ritonavir, cabotegravir, fostemsavir, lenacapavir, daclatasvir, sofobuvir or telaprevir. These are medicines used to treat AIDS, HIV and other viral infections.

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 am being given Rifadin? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rifadin 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 is Rifadin given?

Rifadin is diluted and given by intravenous infusion. Rifadin must only be given by a doctor or nurse.

More instructions can be found in Section 4. How is Rifadin given? in the full CMI.

5. What should I know while being given Rifadin?

Things you should do	• Remind any doctor, dentist, surgeon or pharmacist you visit that you are using Rifadin. • If you have to have any blood or urine tests tell your doctor you are being given Rifadin. • If you are about to be started on a new medicine, including oral contraceptives, tell your doctor you are taking Rifadin.
Things you should not do	• Do not stop using this medicine suddenly.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Rifadin affects you.
Looking after your medicine	• Rifadin is stored in the pharmacy or on the ward. The powder for IV infusion is kept in a cool dry place where the

	temperature stays below 25°C. • Rifadin is used immediately after it has been made up into a solution.

For more information, see Section 5. What should I know while being given Rifadin? 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 Rifadin 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.

Rifadin® Injection (rif-ar-din)

Active ingredient: *rifampicin (rif-am-pee-cin)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Rifadin. **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 Rifadin.**

Where to find information in this leaflet:

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

1. Why am I being given Rifadin?

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

Rifadin is taken with other medicines to treat tuberculosis and is taken to treat leprosy. Rifadin 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 am given Rifadin?

Warnings

Do not take Rifadin 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 use 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).
- you are taking cabotegravir, fostemsavir, lenacapavir for viral infections like HIV.
- you are taking daclatasvir, sofosbuvir or telaprevir for viral infections like hepatitis C virus infections as

rifampicin may reduce the blood levels of the above listed 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 Rifadin with symptoms developing within a few days to a few months following the start of treatment. Stop using Rifadin 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 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 Rifadin. 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)
- 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.

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

Contraception in males and females

If you are a man or an adolescent able to father a child, you should use effective contraceptive measures so that you do not conceive a child for the duration of treatment as well as for 3 months after stopping treatment.

If you are a woman or an adolescent able to get pregnant, you should use effective contraceptive measures for the duration of treatment and for 6 months after stopping treatment.

Rifadin may make the hormonal contraceptives ("birth control pill") work less well. This means you should instead use other methods (barrier methods of contraception) during Rifadin treatment.

If you have any questions or are unsure about this, talk to your doctor or pharmacist.

It is not known if fertility could be impaired while using Rifadin.

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 Rifadin and affect how it works.

Rifadin 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

- cabotegravir, fostemsavir, lenacapavir, daclatasvir, simeprevir, sofosbuvir and telaprevir for the treatment of viral infections.
- 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)
- Cephalosporin antibiotics, such as cefazolin used to treat infection
- oral contraceptives

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

- 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 Rifadin.

4. How is Rifadin given?

Rifadin is diluted and given by intravenous infusion.

Rifadin must only be given by a doctor or nurse.

Your doctor will decide what dose and for how long you will receive Rifadin.

5. What should I know while being given Rifadin?

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 Rifadin exactly as prescribed by your doctor.
- If you have a blood test or urine test, tell your doctor you are taking Rifadin. Rifadin 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 Rifadin.
- 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 being given Rifadin.

Driving or using machines

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

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

After being given Rifadin

Rifadin is stored in the pharmacy or on the ward. The powder for IV infusion is stored in a cool dry place where the temperature stays below 25°C.

When to discard your medicine (as relevant)

Rifadin is used immediately after it has been made up into a solution.

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	**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
• urine, faeces, saliva, sputum, sweat, tears and teeth may be coloured red-orange, yellow or brown by Rifadin. Soft contact lenses may be permanently stained. **Skin or eye-related:** • yellow discolouration of skin or eyes • conjunctivitis • problems with your eyesight **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	

Less serious side effects	What to do
• numbness **Stomach or gut-related:** • heartburn • loss of appetite • nausea • vomiting • upset stomach • gut discomfort • wind • cramps • diarrhoea. Do not take any diarrhoea medicine 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	**Stop using Rifadin and immediately contact a doctor if you experience any of these symptoms.**

Serious side effects	What to do
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.**
Skin-related: • severe red and/or itchy skin, blisters or pimples, bleeding, peeling or bruising of the skin **Blood and lymph related:** • 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	**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
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 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.	

Serious side effects	What to do
• 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 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	**Tell your doctor immediately if you notice any of these serious side effects, particularly if they occur several weeks after stopping treatment with Rifadin.** **These are rare but serious side effects. You may have a rare serious**

Serious side effects	What to do
also be bloody. Do not take any diarrhoea medicine without first checking with your doctor. • fever, in combination with one or both above.	**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 in Australia or in New Zealand at https://pophealth.my.site.com/carmreportnz/s/.

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 Rifadin contains

Active ingredient **(main ingredient)**	600 mg rifampicin per vial
Other ingredients **(inactive ingredients)**	• sodium formaldehyde sulfoxylate • sodium hydroxide Diluent • water for injections

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

What Rifadin looks like

Rifadin is a red powder in a glass vial with sterile water for injections in a glass vial as a solvent (Aust R 156919).

Who distributes Rifadin

Distributed in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

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