

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 Rifinah?

Rifinah contains the active ingredients rifampicin and isoniazid. Rifinah is used to treat tuberculosis.

For more information, see Section [1. Why am I taking Rifinah?](#) in the full CMI.

2. What should I know before I take Rifinah?

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

Do not take Rifinah if you have jaundice.

Do not take Rifinah if you are taking saquinavir or ritonavir. 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 Rifinah?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rifinah 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 Rifinah?

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

More instructions can be found in Section [4. How do I take Rifinah?](#) in the full CMI.

5. What should I know while taking Rifinah?

Things you should do	<ul style="list-style-type: none">• If you are about to be started on a new medicine, including oral contraceptives, tell your doctor you are taking Rifinah.• Remind any doctor, dentist, surgeon, or pharmacist you visit that you are taking Rifinah.• You should see your doctor monthly for a check-up.• If you have a blood or urine test, tell your doctor you are taking Rifinah.• Avoid foods containing tyramine and histamine, such as histamine tablets, cheese, red wine, tuna and other tropical fish.• Continue taking Rifinah exactly as prescribed by your doctor.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine because you feel better.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Rifinah affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Store Rifinah in a cool dry place away from moisture, heat or sunlight.

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

6. Are there any side effects?

Side effects include, loss of appetite, nausea, heartburn, upset stomach, wind, cramps, dizziness, fatigue, muscle weakness, numbness. Serious side effects include allergic reactions, 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.

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.

Rifinah®

Active ingredients: (rifampicin and isoniazid)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Rifinah. **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 Rifinah.**

Where to find information in this leaflet:

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

1. Why am I taking Rifinah?

Rifinah contains the active ingredients rifampicin and isoniazid. Rifinah is an anti-tuberculosis medicine. It kills the bacteria that causes tuberculosis.

Rifinah is used to treat tuberculosis.

2. What should I know before I take Rifinah?

Warnings

Do not take Rifinah if:

- you are allergic to rifampicin or other similar antibiotics such as rifabutin or rifaximin.
- you are allergic to isoniazid.
- 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 have yellowing of the skin and eyes (jaundice).
- you are taking saquinavir or ritonavir. These medicines are used to treat acquired immune deficiency syndrome (AIDS) and human immunodeficiency virus (HIV) infections.

Check with your doctor if you:

- have any other medical conditions
- have problems with your liver including liver disease
- have hepatitis.
- drink alcohol daily.
- have problems with your kidney
- have a problem with bleeding or a tendency to bruise easily.
- inject yourself with drugs.
- have porphyria.
- 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 Rifinah. Soft contact lenses may be permanently stained.

- have diabetes
- are malnourished or underweight
- have Vitamin B6 (pyridoxine) deficiency
- if you experience reappearance or worsening of symptoms of tuberculosis (see section [6. Are there any side effects](#))
- take any medicines for any other condition

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Elderly, Malnourished or Diabetic

Check with your doctor if you are elderly, malnourished, or have diabetes as you may need Vitamin B6 therapy while you are taking Rifinah.

Black or Hispanic Women

Check with your doctor if you are a black or Hispanic woman because you may be at an increased risk of hepatitis.

Children

Rifinah is not recommended for children.

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.

Do not take Rifinah with saquinavir or ritonavir. These medicines are used to treat acquired immune deficiency syndrome (AIDS) and human immunodeficiency virus (HIV) infections.

Rifinah should not be taken with the following medicines:

- halothane, a general anaesthetic
- medicines used to treat Hepatitis C, such as daclatasvir, simeprevir, sofosbuvir and telaprevir
- cephalosporin antibiotics, such as cefazolin used to treat infection
- oral contraceptives

Rifinah and some medicines may interfere with each other and affect how they work.

- antacids

- levothyroxine, a medicine used to treat thyroid deficiency
- quinine, a medicine used to treat nocturnal cramps
- theophylline, a medicine used to treat breathing difficulties
- medicines to treat diabetes
- medicines to treat nausea or vomiting, such as ondansetron
- irinotecan, a medicine used to treat cancer
- methadone, a medicine used for heroin withdrawal

Hormone-related

- medicines for the treatment or prevention of breast cancer, such as tamoxifen
- oral contraceptives, such as estrogens and levonorgestrol
- medicines such as progesterone for hormone replacement therapy, to treat endometriosis or certain types of cancer

Heart or blood-related

- medicines that thin the blood, such as clopidogrel
- dapsone (an antibiotic)
- medicines that prevent blood clots from forming, such as warfarin
- medicines to lower cholesterol, such as simvastatin and clofibrate
- medicines for treating heart problems including irregular heartbeat
- medicines for treating high blood pressure, such as enalapril

Liver-related

- paracetamol (a pain killer)

Infections or immune system-related

- medicines to treat bacterial infections, such as antibiotics
- medicines to treat fungal infections, such as ketoconazole
- medicines used to treat tuberculosis and leprosy, such as dapson and p-aminosalicylic acid (PAS)
- medicines for treating human immunodeficiency virus (HIV)
- medicines used to treat malaria, such as quinine and atovaquone
- medicines to treat inflammation, such as prednisolone, hydrocortisone, and betamethasone
- medicines used to keep the body from rejecting transplanted organs, such as ciclosporin
- praziquantel, a medicine used to treat worm infections

Mental health, brain or pain-related

- medicines to treat mental illnesses, such as anxiety, depression, or psychoses, such as haloperidol, amitriptyline, nortriptyline, and diazepam
- medicines used to control or prevent seizures, such as phenytoin and carbamazepine
- medicines that can cause sedation

- riluzole, a medicine used to treat motor neurone disease
- narcotic analgesics, such as codeine and morphine used to treat 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 Rifinah.

4. How do I take Rifinah?

How much to take

- Patients weighing less than 50 kg should take a single dose of three 150/100 mg tablets once per day.
- Patients weighing more than 50 kg should take a single dose of two 300/150 mg tablets once per day.
- Swallow Rifinah tablets whole with a glass of water.
- Follow the instructions provided when Rifinah was prescribed, including the number of days it should be taken.
- If you need to take an antacid, take it at least 1 hour after your dose of Rifinah.

When to take Rifinah

- Rifinah should be taken once per day on an empty stomach at least 30 minutes before a meal or 2 hours after a meal.

If you forget to take Rifinah

Rifinah should be taken regularly at the same time each day.

If you miss your dose at the usual time and 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 take too much Rifinah

If you think that you have taken too much Rifinah, you may need urgent medical attention.

You should immediately:

- phone the National Poisons Centre (by calling 0800 764 766), 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 Rifinah you may experience nausea, vomiting, stomach pain, itching, headache, tiredness, dizziness, swelling, fast or uneven heartbeat or other problems with heartbeating or other problems with your heartbeat, slurred speech, blurred vision or seeing things that are not there (hallucinations).

5. What should I know while taking Rifinah?

Things you should do

- Avoid foods containing tyramine and histamine, such as cheese, red wine, tuna, and other tropical fish. These foods may interact with isoniazid causing headache, sweating, flushing, fast, fluttering or pounding heartbeat, dizziness, lightheadedness, or fainting.
- 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.
- If you have a blood test or urine test, tell your doctor you are taking Rifinah. Rifinah 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 Rifinah.
- Continue taking Rifinah exactly as prescribed by your doctor.

Call your doctor straight away if you:

- become pregnant or intend to become pregnant
- are breastfeeding or intend to breastfeed

Remind any doctor, surgeon, dentist, or pharmacist you visit that you are taking Rifinah.

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 Rifinah affects you.

Rifinah could cause dizziness and other effects which may affect your ability to perform certain tasks. Do not drive or operate machinery if you experience these symptoms.

Drinking alcohol

Tell your doctor if you drink alcohol.

Daily use of alcohol may put you at greater risk of getting hepatitis.

Looking after your medicine

- Store below 25°C

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
- do not store it in the car or on windowsills.

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
<p>General:</p> <ul style="list-style-type: none"> dizziness fever problems with your period urine, faeces, saliva, sputum, sweat, tears and teeth may be coloured red-orange, yellow or brown by Rifinah. Soft contact lenses may be permanently stained swelling of the breasts in males <p>Central nervous system-related:</p> <ul style="list-style-type: none"> headache difficulty in concentrating confusion mental health problems <p>Skin or eye-related:</p> <ul style="list-style-type: none"> yellow discolouration of skin or eyes flushing itching with or without a rash <p>Thrush-related:</p> <ul style="list-style-type: none"> 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. <p>Muscle or nerve-related:</p> <ul style="list-style-type: none"> muscle weakness poor coordination pain in the fingers or toes numbness <p>Stomach or gut-related:</p> <ul style="list-style-type: none"> 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. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> severe red and/or itchy skin, blisters or pimples, bleeding, peeling or bruising of the skin itching, weakness, tiredness, loss of appetite, nausea, vomiting, stomach or gut pain, yellowing of the eyes or skin or dark urine blood in the urine or any other urination disturbances severe bleeding or bruising more easily than normal 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. shortness of breath and wheezing fever, chills, headache, or dizziness bone pain develop itching with swelling or skin rash or difficulty breathing, or if you turn yellow severe pain in the gut or stomach and back (pancreatitis) enlarged lymph nodes problems with your blood such as low levels of platelets or abnormal levels of white blood cells diarrhoea, dermatitis and dementia. These are symptoms of pellagra (Vitamin B3 deficiency) joint pain and swelling <p>Allergy-related:</p> <ul style="list-style-type: none"> swelling of the face, lips, tongue or throat which may cause difficulty in breathing or swallowing 	<p>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.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> 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 reappearance or new occurrence of symptoms of tuberculosis, following initial improvement in treatment which can occur several weeks or months after treatment initiation. Symptoms may include fever, fatigue, weight loss, excessive night sweating 	<p>Tell your doctor immediately if you notice any of these serious side effects, particularly if they occur several weeks after stopping treatment with Rifinah.</p>

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 at <https://nzphvc.otago.ac.nz/reporting/>.

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 Rifinah contains

Active ingredients (main ingredients)	<p>Each 150/100 mg tablet contains 150 mg of rifampicin and 100 mg of isoniazid.</p> <p>Each 300/150 mg tablet contains 300 mg of rifampicin and 150 mg of isoniazid.</p>
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> microcrystalline cellulose magnesium stearate calcium stearate sodium lauryl sulfate carmellose sodium acacia gelatin magnesium carbonate titanium dioxide kaolin purified talc

	<ul style="list-style-type: none"> sucrose colloidal anhydrous silica povidone carnauba wax colophony hard paraffin white beeswax erythrosine (150/100 mg tablet only) sunset yellow aluminium lake (300/150 mg tablet only)
Potential allergens	Not applicable

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

Rifinah 150/100 mg tablets and 300/150 mg tablets contain sucrose.

What Rifinah looks like

Rifinah 150/100 mg tablets are pink, curved, round, smooth, sugar-coated tablets.

Rifinah 300/150 mg tablets are orange, capsule-shaped, sugar-coated tablets.

Rifinah are packed in blister packs of 100 tablets.

Who distributes Rifinah

sanofi-aventis new zealand limited

56 Cawley St

Ellerslie

Auckland, New Zealand

Toll Free Number (medical information): 0800 283 684

MedInfo.Australia@sanofi.com

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