

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Rifadin® 100mg/5ml Oral Suspension

rifampicin

sanofi



Is this leaflet hard to see
or read?

Phone 0800 035 2525 for help

Important things you need to know about Rifadin Oral Suspension

- It is very important that you take Rifadin Oral Suspension exactly as your doctor has told you. There is a chance of you having a severe and dangerous allergic reaction if you do not take your Oral Suspension each day as you are told
- You must keep taking it until your doctor tells you to stop
- If you are taking any other medicines, including medicines you have bought from the pharmacy or shop, you must make sure your doctor knows
- Rifadin Oral Suspension makes all your body fluids an orange or red colour. Do not worry, this is normal and not harmful
- Take Rifadin Oral Suspension on an empty stomach. This means at least 30 minutes before food or 2 hours after food
- If you get a temperature, are sick, begin to feel more unwell, lose your appetite or have yellowing of the skin, gums or eyes, you must talk to your doctor straight away

Read the rest of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Rifadin Oral Suspension is and what it is used for
2. What you need to know before you take Rifadin Oral Suspension
3. How to take Rifadin Oral Suspension
4. Possible side effects
5. How to store Rifadin Oral Suspension
6. Contents of the pack and other information

1. What Rifadin Oral Suspension is and what it is used for



Rifadin Oral Suspension contains a medicine called rifampicin. It belongs to a group of medicines called anti-bacterials. It works by killing the bacteria that cause infections.

Rifadin Oral Suspension is used to treat the following bacterial infections:

- Tuberculosis (also known as TB) alongside other medicines
- Leprosy alongside other medicines
- Brucellosis alongside other medicines
- Legionnaires Diseases alongside other medicines
- *Haemophilus Influenzae*
- Other serious bacterial infections

Rifadin Oral Suspension can also be used to stop the following infections from developing:

- Meningitis
- *Haemophilus Influenzae* in children aged 4 years or younger

2. What you need to know before you take Rifadin Oral Suspension



Do not take Rifadin Oral Suspension if:

- X You are allergic (hypersensitive) to
 - rifampicin
 - any of the other ingredients of the Rifadin Oral Suspension (see section 6)Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- X You have yellowing of the skin and eyes (jaundice)
- X You are taking saquinavir or ritonavir for an HIV infection (see 'Other medicines and Rifadin Oral Suspension' below)
- X You are taking medicine called lurasidone (medicine for schizophrenia and bipolar disorders), as rifampicin may reduce the blood levels of lurasidone

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rifadin Oral Suspension.



Warnings and precautions

Talk to your doctor or pharmacist before taking Rifadin Oral Suspension if:

- ▲ You have liver problems
- ▲ You have any kidney problems and if you are having more than 600mg rifampicin per day
- ▲ You have diabetes. Your diabetes may become more difficult to control while taking this medicine
- ▲ You feel numb or weak in your arms and legs (peripheral neuropathy)



- ▲ You are under weight or malnourished
 - ▲ You have a rare blood problem called ‘porphyria’
 - ▲ You have a problem with bleeding or a tendency to bruise easily
 - ▲ You have a history of lung inflammation (interstitial lung disease/pneumonitis)
 - ▲ Your symptoms of tuberculosis return or get worse (see section 4 Possible side effects)
 - ▲ You develop a rash or experience any symptoms of thrombotic microangiopathy during your treatment (see section 4 Possible side effects)
 - ▲ You wear contact lenses. Taking Rifadin Oral Suspension may permanently stain soft contact lenses
 - ▲ The person taking this medicine is a child
 - ▲ You are aged 65 years or older
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Rifadin Oral Suspension.

Lung inflammation

Inform your doctor immediately while taking this medicine if you develop new or sudden worsening of shortness of breath, possibly with a dry cough or fever 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.

Liver problems

You should not take rifampicin, a component of Rifadin Oral Suspension, if 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 rifampicin with symptoms developing within a

few days to a few months after the start of treatment. **Stop using rifampicin and contact a doctor** if you have symptoms of liver problems (see section 4 Possible side effects).

Serious skin reactions

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported with the use of Rifadin Oral Suspension.

- SJS/TEN can appear initially as reddish target spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.
- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities

The highest risk for occurrence of serious skin reactions is within 2 days to 2 months after treatment initiation depending on the condition. **If you develop a serious rash or another of these skin symptoms, stop taking Rifadin Oral Suspension and contact your doctor or seek medical attention immediately.**

Blood Tests

Your doctor will need to check your blood before you take this medicine. This will help your doctor know if any changes happen to your blood after taking this medicine. You may also need to have regular blood tests to check how your liver is working.



Other medicines and Rifadin Oral Suspension

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Rifadin Oral Suspension can affect the way some other medicines work. Also, some medicines can affect the way Rifadin Oral Suspension works.

Tell your doctor or pharmacist if you are pregnant and planning or required to undergo pregnancy termination using mifepristone.

In particular, do not take this medicine, and tell your doctor, if you are taking:

- X Saquinavir or ritonavir used for HIV infection
- X Lorazepam used for schizophrenia and bipolar disorders

The following medicines can make Rifadin Oral Suspension work less well:

- Antacids used for indigestion. Take Rifadin Oral Suspension at least 1 hour before taking antacids
- Other medicines used for TB such as P-aminosalicylic acid (PAS). PAS and Rifadin Oral Suspension should be taken at least 8 hours apart

Tell your doctor if you are taking any of the following medicines:

Heart and blood medicines

- Medicines for high blood pressure
- Medicines for heart problems or to control your heartbeat

- Medicines used to thin the blood such as warfarin and clopidogrel
- Medicines used to lower cholesterol
- Water tablets (diuretics) such as eplerenone

Mental health, epilepsy and motor neurone medicines

- Medicines for thought disorders known as 'antipsychotics' such as haloperidol
- Medicines to calm or reduce anxiety (hypnotics, anxiolytics)
- Medicines to help you sleep (barbiturates)
- Medicines used for epilepsy such as phenytoin
- Some medicines used for depression such as amitriptyline and nortriptyline
- Riluzole - used for motor neurone disease

Medicines for infections and the immune system

- Some medicines used for viral infections such as indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, nevirapine, daclatasvir, simeprevir, sofosbuvir and telaprevir
- Medicines used for fungal infections
- Medicines used for bacterial infections (antibiotics)
- Dapsone (an antibiotic) with rifampicin may cause haematological toxicity including a decrease in bone marrow and blood cells, and methaemoglobinaemia (decrease in oxygen in your blood caused by changes in red blood cells)
- Medicines used for lowering your immune system such as ciclosporin, sirolimus and tacrolimus
- Praziquantel - used for tapeworm infections
- Atovaquone - used for pneumonia

Hormone and cancer medicines

- Some hormone medicines (oestrogen, systemic hormones, progestogens) used for contraception or some types of cancer such as ethinyloestradiol, levonorgestrel or dydrogesterone

- Some hormone medicines (anti-oestrogens) used for breast cancer or endometriosis such as tamoxifen, toremifene and gestrinone
- Some medicines used for cancer (cytotoxics) such as imatinib
- Levothyroxine (thyroid hormone) used for thyroid problems
- Irinotecan - used for cancer

Pain, inflammation and gout medicines

- Non-steroidal anti-inflammatory drugs (NSAIDs) such as etoricoxib, aspirin and indomethacin
- Medicines used for pain such as codeine, morphine, fentanyl or pethidine.
- Paracetamol and rifampicin can increase the risk of liver damage
- Corticosteroids used for inflammation such as hydrocortisone, betamethasone and prednisolone
- Methadone - used for heroin withdrawal

Other medicines

- Medicines used for diabetes
- Medicines used to relax muscles before surgery (anaesthetics) such as halothane
- Some medicines used for feeling sick or being sick such as ondansetron and aprepitant
- Other antibiotic medicines such as cefazolin
- Quinine - used for malaria
- Theophylline - used for wheezing or difficulty in breathing

Taking Rifadin Oral Suspension with food and drink

Take Rifadin Oral Suspension on an empty stomach. This means at least 30 minutes before food or 2 hours after food.

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if you are pregnant, plan to get pregnant or think you are pregnant.

Rifadin Oral Suspension may make the contraceptive "pill" work less well. This means you should change to a different type of contraception. Instead, you must use a reliable barrier method of contraception such as condoms or the "coil" while taking Rifadin Oral Suspension. If you have any questions or are unsure about this talk to your doctor or pharmacist.

You should not breast-feed if you are taking Rifadin Oral Suspension. This is because small amounts may pass into the mothers' milk. If you are breast-feeding or planning to breast feed, talk to your doctor or pharmacist before taking any medicine.



Driving and using machines

You may feel dizzy or faint, have problems with vision or have other side effects that could affect your ability to drive while taking this medicine. If this happens, do not drive or use any tools or machines.

Rifadin Oral Suspension contains:

- **Sucrose:** This medicine contains 12 g of sucrose per 30 ml dose. This should be taken into account in patients with diabetes mellitus. May also be harmful to teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Sodium:** This medicine contains less than 1mmol sodium (23mg) per daily dose, that is to say essentially 'sodium-free'.
- **Sodium metabisulfite:** These may rarely cause severe allergic reactions (hypersensitivity) and difficulty in breathing (bronchospasm). This is more likely to happen if you have a history of asthma or allergies. Tell a doctor or nurse straight away if you get a rash, swallowing or breathing problems and swelling of your lips, face, throat or tongue.

Methyl-p-hydroxybenzoate and propyl-p-hydroxybenzoate:

these may cause an allergic reaction (this might not happen straight away). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- **Ethanol:** This medicine contains 28.5 mg of alcohol (ethanol) in each 30 ml dose which is equivalent to 0.95 mg/ml (0.1% w/v). The amount in 30 ml of this medicine is equivalent to less than 1 ml beer or wine. The small amount of alcohol in this medicine will not have any noticeable side effects.

- **Potassium:** This medicine contains less than 1 mmol (10.4 mg) potassium per 30 ml dose. This is to be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take Rifadin Oral Suspension

Always take Rifadin Oral Suspension exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Keep taking this medicine

- You must take this medicine each day for the whole time the doctor has told you to take it
- **Do not** stop and start taking the Oral Suspension. This may increase the risk of side effects and your infection will not be treated properly

How to take the Oral Suspension

- Shake well before use;
- Take this medicine by mouth;
- Take at least 30 minutes before a meal or 2 hours after a meal;
- Only use the measuring cup supplied in the Rifadin Oral Suspension pack to measure your dose. Do not use the cup to measure other medicinal products;
- You will be able to measure the dose in the measuring cup supplied with the Oral Suspension;

- The measurement graduations of the cup show you how to measure between 2.5ml (50mg) and 7.5ml (150mg);
- You may need to measure out more than one 7.5ml (150mg) cup to make up your dose. Talk to your doctor or pharmacist if you are unsure how much to measure;
- If the dose is less than 2.5ml (50mg), talk to your doctor or pharmacist about how to measure the dose;
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take

How much you will be given will depend your age and on the type of illness

Tuberculosis (TB)

- Rifadin should be given with at least one other medicine for TB
- The usual dose is:
 - Patients weighing less than 50kg: A single daily dose of 450mg
 - Patients weighing more than 50kg: A single daily dose of 600mg
 - Children: 10mg - 20mg per kilogram of body weight each day. The maximum dose is 600mg each day

Leprosy

- Rifadin should always be given with at least one other medicine for leprosy
- Your doctor may prescribe a monthly or daily dose.
- The usual dose is:
 - Patients weighing less than 50kg: A single daily dose of 450mg
 - Patients weighing more than 50kg: A single daily dose of 600mg

Brucellosis, Legionnaires Disease or other serious bacterial infections

- Rifadin should be used together with another antibiotic

The amount you are given will depend on how severe your infection is:

- Adults: 600mg - 1200mg each day. The dose is given in 2 - 4 divided doses

Stopping the development of Meningitis

- The usual dose is:
 - Adults: 600mg twice each day for two days
 - Children (1 -12 years): 10mg per kilogram of bodyweight, twice each day for two days
 - Children (3 months - 1 year): 5mg per kilogram twice each day for two days

Stopping the development of Haemophilus Influenzae:

- Everybody in the same house needs to be treated under the doctors direction
- The usual dose is:
 - Adults and Children: 20mg per kilogram body weight each day for four days. No more than 600mg should be given.
 - Neonates (1 month): 10mg/kg each day for 4 days

Elderly patients

Your doctor may need to monitor you more closely.

People with liver problems

You should not be given any more than 8mg per kilogram of body weight each day.

If you take more Rifadin Oral Suspension than you should

If you take more Rifadin Oral Suspension than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

You may feel sick (nausea), be sick (vomiting), have stomach pain, itching or a headache. You may also feel tired, sleepy, dizzy or light-headed. Other signs of taking too much includes swelling of the face, eyes or eyelids, slurring of speech, difficulty breathing, fast heartbeat, uneven heartbeats, fits and heart attack.

If you forget to take Rifadin Oral Suspension

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. **Do not** take a double dose to make up for the forgotten dose.

If you stop taking Rifadin Oral Suspension

Keep taking Rifadin Oral Suspension until your doctor tells you to stop. Do not stop taking Rifadin Oral Suspension just because you feel better. If you stop, your infection may get worse.

Tests

Taking Rifadin Oral Suspension may affect the results of some blood tests. In particular, tests for folate, vitamin B12 and liver function. If you are going to have a blood test, it is important to tell your doctor that you are taking Rifadin Oral Suspension.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Rifadin Oral Suspension can cause side effects, although not everybody gets them.

Stop taking and go to a hospital straight away if you notice any of the following serious side effects:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, wheezing, swelling of your lips, face, throat or tongue.
- Nausea (feeling sick) or vomiting (being sick), fever, feeling tired, loss of appetite (anorexia), dark-coloured urine, light-coloured faeces, yellowing of the skin or whites of the eyes, itching, rash or upper stomach pain. These symptoms may be signs of liver injury.
- Serious skin rashes including Steven-Johnson syndrome, toxic epidermal necrolysis. These

can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. **See also section 2.**

- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). **See also section 2.**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis). **See also section 2.**
- You bruise more easily than usual. Or you may have a painful rash of dark red spots under the skin which do not go away when you press on them (purpura). This could be because of a serious blood problem
- You have severe bleeding (haemorrhage)
- Paradoxical drug reaction - Symptoms of tuberculosis can return, or new symptoms can occur after initial improvement during treatment. Paradoxical reactions have been reported as early as 2 weeks and as late as 18 months after beginning anti-tuberculosis treatment. Paradoxical reactions are typically associated with fever, swollen lymph nodes (lymphadenitis), breathlessness, and cough. Patients with paradoxical drug reaction can also experience headaches, loss of appetite, and weight loss.
- You have chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark coloured urine. This could be signs of a serious type of anaemia

• You have blood in your urine or an increase or decrease in amount of urine you produce.

You may also get swelling, especially of the legs, ankles or feet. This may be caused by serious kidney problems

- You have a sudden severe headache. This could be a sign of bleeding in the brain
- New or sudden worsening of shortness of breath and wheezing, possibly with a cough or fever. These could be symptoms of inflammation of the lungs (interstitial lung disease/pneumonitis).
- You get confused, sleepy, cold clammy skin, shallow or difficult breathing, a racing heartbeat or your skin is paler than normal. These could be signs of shock
- You get more infections more easily than normal. Signs include fever, sore throat or mouth ulcers. This could be because you have a low number of white blood cells
- You have bleeding from your nose, ear, gums, throat, skin or stomach. Signs may include a feeling of tenderness and swelling in your stomach, purple spots on your skin and black or tar-like stools
- Mental problems with unusual thoughts and strange visions (hallucinations)
- Severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called 'Pseudomembranous colitis'
- Flu-like symptoms including chills, fever, headache, dizziness and bone pains
- Inflammation of the liver - yellowing of the skin and white part of eyes, increase in the blood level of liver enzymes
- 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.

Tell your doctor as soon as possible if you have any of the following side effects:

- Water retention (oedema) which may cause swollen face, stomach, arms or legs
- Muscle weakness or pain or loss of muscle reflexes
- Dizziness, feel lightheaded and faint especially when you stand or sit up quickly (due to low blood pressure)
- Swollen fingers, toes or ankles
- Being unable to concentrate, feeling nervous, irritable or depressed
- Feeling very tired and weak or difficulty sleeping (insomnia)
- Short-term memory loss, anxiety, being less alert or responsive
- Wasting of muscles or other body tissues
- Weight loss, night sweats and fever. These could be signs of a blood condition called eosinophilia
- Feeling sick (nausea) or being sick (vomiting)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Skin flushing or itching
- Irregular periods
- Loss of appetite (anorexia)
- Headache
- Diarrhoea or stomach discomfort

Other side effects you should discuss with your doctor if you are concerned about them

You notice a discolouration (yellow, brown, orange or red colour) in your teeth, urine, sweat, phlegm (sputum), saliva or tears. This is quite common and you need not worry. However, the colour may permanently stain soft contact

lenses. The colour in tears may last for some time after you have stopped having Rifadin Oral Suspension.

Blood tests

A blood test may show changes in the way the liver is working

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rifadin Oral Suspension

Keep this medicine out of the sight and reach of children.

Do not use Rifadin Oral Suspension after the expiry date which is stated on the carton and blister packs after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store the bottle and measuring cup in the original outer carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rifadin Oral Suspension contains

- Each 1ml of Oral Suspension contains 20mg of the active ingredient, rifampicin.

- The other ingredients are agar, sucrose, methyl-p-hydroxybenzoate, propyl-p-hydroxybenzoate, potassium sorbate, sodium metabisulphite, tween 80, raspberry essence (contains small amount of ethanol), saccharin, diethanolamine, purified water

What Rifadin Oral Suspension look like and contents of the pack

Rifadin Oral Suspension is a raspberry flavoured and coloured suspension. It is supplied in a 120ml amber bottle, accompanied by a 7.5ml (150mg) measuring cup.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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This leaflet does not contain all the information required about your medicine.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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