

Rifadin® 100mg/5ml

Oral Suspension

Rifampicin

Is this leaflet hard to see or read?

Phone 01 403 5600 for help.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Rifadin is and what it is used for

Rifadin 100mg/5ml Oral Suspension is one of a group of medicines called antibiotics. It is used to treat tuberculosis (also known as TB) and other similar types of infection.

2. Before you take Rifadin

Do not take Rifadin if:

- You are allergic (hypersensitive) to rifampicin or any of the other ingredients.
- You have yellowing of the skin and eyes (jaundice).
- You are taking saquinavir or ritonavir for HIV infection (see 'Taking other medicines' section below).

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

Warnings and precautions

Inform your doctor immediately while taking this medicine

- If your symptoms of tuberculosis return or get worse (see 4. Possible side effects)

- 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

Take special care with Rifadin

Tell your doctor or pharmacist if:

- If you have a history of lung inflammation (interstitial lung disease/pneumonitis)
- You have liver or kidney problems
- If you have a problem with bleeding or tendency to bruise easily
- If you are taking other antibiotics at the same time
- You have a rare blood problem called 'porphyria'
- Rifadin may produce a discolouration (yellow, orange, red, brown) of the teeth, urine, sweat, sputum and tears. If you wear contact lenses please note that Rifadin may permanently stain soft contact lenses.
- If you have severe skin reaction such as severe extensive skin damage (separation of the epidermis and superficial mucous membranes) (toxic epidermal necrolysis, TEN,), Skin blistering, red/purple rash, fever headache, cough and joint pain (Stevens-Johnson syndrome, SJS) or large areas of red, swollen skin with small pus-filled elevations (acute generalized exanthematous pustulosis, AGEP) may occur.
Treatment must be immediately discontinued if any symptoms or signs of AGEP, SJS or TEN are present.
- The person having 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.

Blood Tests

Your doctor will need to check your blood before you are given 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.

Taking other medicines

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

In particular, tell your doctor if you are taking:

- Saquinavir or ritonavir used for HIV infection.
- Other antibiotic medicines such as cefazolin (concomittant use should be avoided as it

may lead to severe blood disorders, which may result in fatal outcome, especially in high doses).

The following medicines can make Rifadin work less well:

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

Tell your doctor or pharmacist 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.
- Some medicines used to thin the blood such as warfarin, clopidogrel.
- Medicine used to lower cholesterol such as simvastatin

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 nortriptyline.

Medicines for infections and the immune system

- Some medicines used for viral infections such as indinavir, efavirenz, ritonavir, saquinavir, zidovudine.
- Medicines used to treat Hepatitis C such as daclatasvir, simeprevir, sofosbuvir, and telaprevir.

Concurrent use of treatment of antiviral hepatitis C drugs and rifadin should be avoided.

- Medicines used for fungal infections.
- Medicines used for bacterial infections (antibiotics).
- Medicines used for lowering your immune system such as ciclosporin and tacrolimus.
- Praziquantel - used for tapeworm infections.
- Atovaquone - used for pneumonia.
- Dapsone: If you are taking dapsone (an antibiotic) with rifampicin, it may cause haematological toxicity including a decrease in bone marrow and blood cells, and methemoglobinemia (decrease in oxygen in your blood caused by changes in red blood cells)

Hormone and cancer medicines

- Some hormone medicines (estrogen, systemic hormones, progestogens) used for contraception.
- Some hormone medicines (anti-estrogens) used for breast cancer or endometriosis such as tamoxifen, toremifene.
- Levothyroxine (thyroid hormone) used for thyroid problems.
- Irinotecan - used for cancer.

Pain, inflammation and gout medicines

- Medicines used for pain.
- Paracetamol: If you are taking paracetamol and rifampicin, it 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.
- Quinine - used for malaria.
- Theophylline - used for wheezing or difficulty in breathing.

Tell your doctor or pharmacist if you are pregnant and planning or required to undergo pregnancy termination using mifepristone (please see pregnancy and breastfeeding)

Taking Rifadin with food and drink

The oral suspension should be taken either 30 minutes before a meal or 2 hours after a meal.

Pregnancy and breast-feeding

Tell your doctor if you are or may be pregnant or are breast feeding.

If you are using oral contraception ("the Pill") it is important that you use an alternative barrier method of contraception or the "coil" whilst taking Rifadin and to continue using this form of contraception for two weeks after finishing your course of treatment. This is because Rifadin may make "the Pill" less effective.

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

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 having this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Rifadin

The oral suspension contains parahydroxybenzoates which may cause allergic reactions (possibly delayed). It also contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm.

Do not use if you have jaundice. The oral suspension also contains 2g of sucrose per 5ml which should be taken into account if you suffer from hereditary fructose intolerance, glucose-galactose malabsorption syndrome or sucrose-isomaltase deficiency.

Rifadin Oral Suspension contains 2g of sucrose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars. Contact your doctor before taking this medicinal product. Rifadin Oral Suspension may also be harmful to teeth.

Rifadin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per mg/ml, that is to say essentially 'sodium-free'.

Rifadin contains alcohol

This medicine contains 4.78 mg of alcohol (ethanol) in each 5 ml which is equivalent to 0.96 mg/ml . The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Rifadin

Your doctor or pharmacist will tell you how much oral suspension to take. The enclosed measuring device is graduated to allow a dose of 2.5 ml, 5 ml or 7.5 ml to be administered.

Tuberculosis

The usual adult daily dose is 30 ml. The usual daily dose for a child over 3 months is: 15 (10-20) mg/kg body weight, however this should not exceed 30 ml.

Impaired Liver Function

Your doctor will probably reduce your dose if you have impaired liver function, usually to no more than 8mg/kg a day.

In elderly patients, your doctor may monitor your dose more closely, especially if you show signs of liver dysfunction.

If you take more Rifadin than you should

If you take more Rifadin 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.

If you forget to take Rifadin

If you forget to take your oral suspension, take it as soon as you remember the same day. If it is nearly time for the next dose then take only that dose and do not take extra to make up for the missed oral suspension.

If you stop taking Rifadin

You should only stop taking the oral suspension if your doctor tells you to. It is essential to take the oral suspension every day and not to stop and start it as this could cause unwanted side effects.

4. Possible Side-effects

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

Common: may affect up to 1 in 10 people

• 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.

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.
- You have a fever and yellowing of the skin or whites of the eyes, feel tired, weak or generally unwell, loss of appetite (anorexia), feeling sick (nausea), being sick (vomiting). These may be early signs of liver problems.
- You get blistering, peeling, bleeding, scaling or fluid filled patches on any part of your skin. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may have a serious skin problem.
- 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).
- 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.
- 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.
- Severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called 'Pseudomembranous colitis'.

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.
- Hair loss.
- 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.

If you experience the following side effects contact your doctor immediately:

- A drug reaction that causes rash, fever inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome). Large areas of red, swollen skin with small pus-filled elevations (acute generalized exanthematous pustulosis, AGEP).
- Severe bleeding.
- Itching, weakness, loss of appetite, nausea, vomiting, abdominal pain, yellowing of eyes or skin or dark urine. These symptoms might be related to a severe liver injury.
- **Not known: frequency cannot be estimated from the available data**
- Inflammation of the lungs (interstitial lung disease/pneumonitis): Tell your doctor immediately if you develop new or sudden worsening of shortness of breath, possibly with a cough or fever.

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.
- Diarrhoea or stomach discomfort.

Other side effects you should discuss with your doctor:

You notice a discolouration (yellow, brown, orange or red colour) in your teeth (which may be permanent), urine, sweat, phlegm (sputum), saliva or tears. The colour may permanently stain soft contact lenses.

If you notice any other side effects not listed in this leaflet talk to your doctor or pharmacist.

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:

HPRA Pharmacovigilance Website: www.hpra.ie

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

5. How to store Rifadin

Do not use Rifadin after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month. Keep out of the reach and sight of children. Your medicine could harm them. Store your medicine in the original package. Do not store above 25°C.

Do not dilute it.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Rifadin contains

The active substance is rifampicin. Each 5 ml dose contains 100 mg of rifampicin. The oral suspension also contains agar, sucrose, methyl parahydroxybenzoate, propyl parahydroxybenzoate, potassium sorbate, sodium metabisulphite, polysorbate 80, raspberry essence (including natural flavourings, glucose oral suspension, ethanol, alpha methylionone), saccharin, diethanolamine and purified water.

What Rifadin looks like and contents of the pack

The oral suspension is raspberry flavoured and coloured. Each bottle contains 120 ml of oral suspension.

Marketing Authorisation Holder and Manufacturer

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