

Package leaflet: Information for the patient

Rifampicin 300 mg Capsules

Read all 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on 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. See section 4.

What is in this leaflet

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

1. What Rifampicin is and what it is used for

Rifampicin belongs to a group of medicines called rifamycin antibiotics. It can be used to treat a variety of infections such as:

- Tuberculosis
- Leprosy
- Legionnaires Disease
- Brucellosis and serious staphylococcal infections

It may also be given to 'carriers', these are people who may be infected but do not have the symptoms of the infections caused by *Haemophilus influenzae* (which causes the flu) and *Neisseria meningitidis* (which causes meningitis).

2. What you need to know before you take Rifampicin

Do not take Rifampicin if you

- are allergic (hypersensitive) to rifampicin or another rifamycin antibiotic or any of the other ingredients of this medicine (listed in section 6)
- have jaundice (yellowing of the skin or whites of the eyes)
- you are taking saquinavir or ritonavir (as you may develop liver problems if you are also taking rifampicin).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Rifampicin if you:

- have or have ever had problems with your liver
- have kidney problems and are taking more than 600 mg of Rifampicin per day
- are diabetic; as your diabetes may become more difficult to control
- have a rare blood problem called porphyria

- are underweight or malnourished, elderly, suffer from liver problems or under 2 years old and also taking isoniazid; your doctor may check your liver function
- your symptoms of tuberculosis return or get worse (see section 4 Possible side effects)
- wear contact lenses. Taking Rifampicin may permanently stain soft contact lenses.
- are vitamin K deficient or have hypoprothrombinemia. Rifampicin may cause vitamin K dependent coagulation and severe bleeding. Monitoring of occurrence of coagulation is recommended for patients at particular bleeding risk.

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

Important information about potentially life-threatening 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 Rifampicin.

- 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 Rifampicin 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.

It is possible that Rifampicin may interfere with some blood tests. If you need a blood test to check bilirubin, folate or vitamin B12 levels tell your doctor you are taking Rifampicin as it may affect your results.

Other medicines and Rifampicin

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, including herbal medicines. This is because Rifampicin can affect the way some other medicines work. Also some medicines can affect the way Rifampicin work.

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

- Saquinavir or ritonavir used for HIV infection

The following medicines can make Rifampicin work less well:

- Antacids used for indigestion. Take Rifampicin at least 1 hour before taking antacids
- Other medicines used for TB such as P-aminosalicylic acid (PAS). PAS and Rifampicin 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)
- 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 (estrogen, systemic hormones, progestogens) used for contraception or some types of cancer such as ethinyloestradiol, levonorgestrel or dydrogesterone
- Some hormone medicines (anti-estrogens) 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 indometacin
- Medicines used for pain such as codeine, morphine, fentanyl or pethidine
- 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. If you are undergoing surgery please inform your doctor before the operation that you are using or have previously used Rifampicin. This is because Rifampicin and some anaesthetics (such as halothane) should not be taken together.
- Some medicines used for feeling sick or being sick such as ondansetron and aprepitant
- Other antibiotic medicines such as cefazolin and isoniazid
- Quinine - used for malaria
- Theophylline - used for wheezing or difficulty in breathing

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

Tell your doctor if you are pregnant or planning to become pregnant. Rifampicin should not be taken during pregnancy as it can affect the growth of your unborn baby and may cause complications to the mother and baby after birth.

Rifampicin may make the contraceptive “pill” work less well. This means you should change to a different type of contraception. You must use a reliable barrier method of contraception such as condoms or the “coil” while taking Rifampicin. 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 Rifampicin. This is because small amounts may pass into the mothers’ milk. If you are breastfeeding 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.

Rifampicin contains lactose

This medicine contains **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Rifampicin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- you should take Rifampicin on an empty stomach, at least 30 minutes before a meal or 2 hours after a meal.
- it is important you finish the course of treatment as directed by your doctor.

The recommended dose for each type of infection is:

Tuberculosis (along with another medicine) Adults

For patients weighing less than 50 kg the usual daily dose is 450 mg, for patients weighing 50 kg or more, the usual daily dose is 600 mg.

Children above 3 months

The recommended daily dose is 15 (10-20) mg/kg body weight, up to a maximum of 600 mg.

Leprosy (along with another medicine) Adults

For patients weighing less than 50 kg the usual daily dose is 450 mg, for patients weighing 50 kg or more, the usual daily dose is 600 mg. A single dose of 600 mg once a month may be given.

Children

For paucibacillary forms, Rifampicin should be administered with dapsone for a period of 6 months. For multibacillary forms, Rifampicin should be administered with dapsone and clofazimine for a period of 12 months. The recommended dose is:

Over 10 years: 450 mg once a month.

Under 10 years: 10 to 20 mg/kg bodyweight once a month.

Legionnaires Disease, brucellosis, serious staphylococcal infections (along with other medicine) The recommended daily dose is 600 mg –1200 mg in 2 to 4 divided doses throughout the day.

Prevention of meningococcal meningitis Adults

The recommended dose is 600 mg twice daily for 2 days

Children

1 month and above: 10 mg/kg body weight every 12 hours for 2 days.

Under 1 month: 5 mg/kg body weight every 12 hours for 2 days.

The dose must not exceed 600 mg/dose.

Prevention of Haemophilus influenzae infection Adults and children 1 month and above

For members of a household exposed to the infection the recommended daily dose is 20 mg/kg body weight, up to a maximum of 600 mg, once daily for 4 days.

Children under 1 month

The recommended dose is 10 mg/kg body weight once daily for 4 days.

Older people

Your doctor may give you a lower dose than those stated above.

Patients with liver problems

You **should not** be given a daily dose of more than 8 mg/kg body weight.

If you take more Rifampicin than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining capsules with you.

If an overdose has been taken, you may suffer from nausea or vomiting (feeling or being sick), stomach pain, itching, headache and an increasing feeling of drowsiness. Patients with severe liver problems may pass out (become unconscious). Other signs of overdose include: swelling of the face, eyes or eyelids, fast or uneven heartbeat, dizziness, fits and heart attack.

If you forget to take Rifampicin

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Rifampicin

Do not suddenly stop taking your medicine even if you feel better as this may cause side effects or your condition may reoccur.

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

4. Possible side effects

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

If any of the following happen, stop taking Rifampicin and tell your doctor immediately or go to your nearest hospital emergency department:

- allergic reactions such as swollen skin or swelling of the face, lips, tongue and/or throat which may cause difficulty breathing or swallowing, shortness of breath and wheezing
- Serious skin rashes including Steven-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN). 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.
- small purple spots or unusual bruising or bleeding of the skin, and/or a sudden, severe headache
- bleeding from your nose, ear, gums, throat, skin or stomach. You may notice a feeling of tenderness and swelling in your stomach, purple spots on your skin and black or tar-like stools
- 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
- severe diarrhoea possibly with blood in the stools
- liver problems which may cause dark urine, pale stools, yellowing of the skin or whites of the eyes (jaundice)
- kidney problems which may cause blood in the urine, a change in the amount of urine passed, and feeling drowsy or weak
- swollen blood vessels in the skin.
- acute generalized exanthematous pustulosis (AGEP) - a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment
- porphyria - symptoms of porphyria may include: abdominal pain, often accompanied by vomiting, hypertension (elevated blood pressure), and tachycardia (an abnormally rapid heart rate).
- adrenal insufficiency - symptoms include: hypoglycaemia (low blood sugar), dehydration, weight loss, and disorientation.

These side effects are serious. You may need medical attention.

Tell your doctor straight away if you notice any of the following side effects:

- fever, chills, headache, dizziness and bone pain
- mental problems causing a change in personality, hallucinations and odd behaviour (psychotic disorder)
- signs of shock such as clammy, cold skin, a racing heartbeat and shallow breathing
- very rare effects include blood changes causing symptoms such as feeling unusually tired, chest pain, sore throat, mouth ulcers.

Tell your doctor straight away if you notice any of these effects.

The following side effects are common (may affect up to 1 in 10 people)

- nausea or vomiting (feeling or being sick)
- blood bilirubin increased, aspartate aminotransferase increased, alanine aminotransferase increased

The following side effects are not known (frequency cannot be estimated from the available data)

- irregular periods, more likely if on long-term treatment.
- your tears, urine, sweat, teeth, phlegm and saliva may discolour (yellow, orange, red, brown). If you wear soft contact lenses rifampicin may permanently stain them
- loss of appetite
- swelling of the legs and ankles (edema)
- muscle weakness, pain or wasting
- flushing
- stomach pain

- itchy skin (dermatitis allergic) with or without a rash
- low blood pressure
- swelling or inflammation of the large intestine
- gastrointestinal disorder
- a woman has heavy bleeding after giving birth (Postpartum haemorrhage), fetal-maternal haemorrhage,
- blood creatinine increased, hepatic enzyme increased.

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 Rifampicin

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

Do not use Rifampicin after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Store in a cool dry place.

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

6. Contents of the pack and other information

What Rifampicin contains

The active substance is rifampicin.

The other ingredients are ascorbic acid, lactose monohydrate (see section 2 “Rifampicin contains lactose”), talc and magnesium stearate. The capsule shell includes indigotine (E132), titanium dioxide (E171), gelatine, erythrosine (E127) and red iron oxide (E172). The capsule printing ink includes shellac, iron oxide black (E172), propylene glycol and ammonium hydroxide.

What Rifampicin looks like and contents of the pack

150 mg: Your medicine comes as a hard capsule with a dark blue body and a maroon cap, printed in black ink “RN150” on the body and “G” on the cap (The capsule contents are brick red).

300 mg: Your medicine comes as a hard capsule with a pink body and maroon cap, printed in black ink “RN300” on the body and “G” on the cap (The capsule contents are brick red).

Rifampicin is available in plastic bottles (with an optional filler) of 5, 7, 8, 10, 14, 15, 16, 20, 21, 25, 28, 30, 56, 60, 84, 90, 100, 250 and 500 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

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