

Rimactane® 300 mg Capsules

(rifampicin)

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PATIENT INFORMATION LEAFLET

Important things you need to know about Rimactane 300 mg Capsules

- It is very important that you take Rimactane 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 Rimactane each day as you are told.
- You must keep taking Rimactane 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.
- Rimactane makes all your body fluids an orange or red colour. Do not worry – this is normal and not harmful.
- Take Rimactane 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 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 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 of the side-effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is available using the above name but will be referred to as Rimactane throughout this leaflet.

What is in this leaflet:

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

1. WHAT RIMACTANE IS AND WHAT IT IS USED FOR

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

Rimactane is used to treat the following bacterial infections:

- In combination with other drugs for the treatment and prevention of tuberculosis (also known as TB), an infectious disease mainly affecting the lungs, and some other infections
- Prevention of meningococcal meningitis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RIMACTANE

Do not take Rimactane if you:

- are allergic to active substance or to any of the other ingredients of this medicine (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- have jaundice – yellowing of the skin or whites of the eyes caused by liver or blood problems.
- are taking saquinavir or ritonavir for an HIV infection (see ‘Other medicines and Rimactane’ section below).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Rimactane if you:

- have a rare blood disorder called ‘porphyria’.
- have a problem with bleeding or a tendency to bruise easily
- have or previously had any liver problem.
- have any kidney problems and if you are having more than 600 mg rifampicin per day.
- have a history of alcohol dependence.
- have taken a course of rifampicin in the past.
- have diabetes. Your diabetes may become more difficult to control while taking this medicine.
- feel numb or weak in your arms and legs (peripheral neuropathy).
- are under weight or malnourished.
- wear contact lenses. Taking Rimactane may permanently stain soft contact lenses. Do not wear soft contact lenses whilst you are taking this medicine and for one week after stopping treatment.
- the person taking this medicine is a child.
- are aged 65 years or older.

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

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.

Take special care with Rimactane

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 Rimactane.

- 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 Rimactane and contact your doctor or seek medical attention immediately.

Other medicines and Rimactane

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 Rimactane can affect the way some other medicines work. Also some medicines can affect the way Rimactane 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 Rimactane work less well:

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

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

- for high blood pressure, heart disorders or to control your heartbeat such as
 - digoxin
 - antiarrhythmics (e.g. quinidine, lorcaïnide, disopyramide)
 - beta blockers (e.g. propranolol, atenolol)
 - calcium channel blockers (e.g. nifedipine, amlodipine, verapamil)
 - ACE inhibitors (e.g. enalapril, imidapril)
 - vasodilators (e.g. bosentan)
 - water tablets (diuretics) such as eplerenone
- used to thin the blood such as warfarin
- used to lower cholesterol
- used to reduce blood lipid level such as simvastatin, fluvastatin.

Mental health, epilepsy and motor neurone medicines

- for thought disorders known as ‘antipsychotics’ such as haloperidol
- to calm or reduce anxiety (hypnotics, anxiolytics)
- to help you sleep (barbiturates)
- used for epilepsy such as phenytoin
- used for depression such as amitriptyline and nortriptyline
- riluzole - used for motor neurone disease.

Medicines for infections and the immune system

- used for viral infections such as indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, nevirapine, daclatasvir, simeprevir, sofosbuvir and telaprevir
- used for fungal infections
- used for bacterial infections (antibiotics)
- 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 ethinylloestradiol, levonorgestrel or dydrogesterone
- some hormone medicines (anti-estrogens) used for breast cancer or endometriosis such as tamoxifen, toremifene and gestrinone
- 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
- 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

- used for diabetes
- used to relax muscles before surgery (anaesthetics) such as halothane
- 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
- fesoterodine - used for overactive bladder
- tadalafil - used for impotence
- cimetidine - used for ulcer-healing drugs.

Taking Rimactane with food and drink

Take Rimactane on an empty stomach. This means at least 30 minutes before food or 2 hours after food. Do not drink any alcohol while you are taking Rimactane.

Pregnancy and breast-feeding

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

Rimactane 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 Rimactane. 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 Rimactane. 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.

Rimactane 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 RIMACTANE

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

Take your medicine on an empty stomach. The best time to take it is half an hour before a meal with water.

For the treatment of tuberculosis:

Adult: 450 mg or 600 mg Rimactane daily, depending on your weight, for 6-9 months.

Children: 10 mg to 20 mg per kg of body weight daily for 6-9 months. The maximum dose is 600 mg each day.

Occasionally the Rimactane dose is given 2-3 times a week instead of daily.

Rimactane must always be taken with at least one and preferably two other anti-tuberculosis drugs.

For the prevention of meningococcal meningitis:

Adults: 600 mg twice a day for 2 days.

Children over 1 month: 10 mg per kg every 12 hours for 2 days.

Children under 1 month: 5 mg per kg every 12 hours for 2 days.

The maximum dose is 600 mg.

If you are not sure how many capsules to take, ask your doctor or pharmacist.

Second time (or subsequent) treatment

If you have been treated with Rimactane before, your doctor will probably start with a smaller dose.

If you take more Rimactane than you should

If you take more Rimactane 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 Rimactane

If you forget to take a tablet you should take it as soon as you remember. However, if this is within 2 hours of your next dose you should skip the missed capsule and carry on taking the rest of your capsules as usual.

Do not take a double dose to make up for a forgotten tablet.**If you stop taking Rimactane**

Keep taking Rimactane until your doctor tells you to stop. Do not stop taking Rimactane just because you feel better. If you stop, your infection may get worse. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Tests

Taking Rimactane 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 Rimactane.

4. POSSIBLE SIDE EFFECTS

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

Like all medicines, Rifampicin 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
- 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
- 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)
- 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
- Shortness of breath and wheezing
- 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

Talk to your doctor straight away if you notice any of the following serious side effects:

- 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

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 or being sick

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
- Loss of appetite (anorexia)
- Headache

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

- You notice a discoloration (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 Rifampicin 300mg capsules.

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 Yellow Card Scheme Website: 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 RIMACTANE

Keep out of the sight and reach of children.

Do not take Rimactane after the expiry date which is printed on the pack. The expiry date refers to the last day of that month.

Store in the original container to protect from heat and moisture. Do not store above 30°C.

If the capsules become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Return any unused capsules to your pharmacist.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Rimactane contains**

The active substance in Rimactane is rifampicin.

Each capsule contains 300 mg rifampicin.

Other ingredients are: calcium stearate, lactose and black printing ink.

What Rimactane looks like and the contents of the pack

Rimactane capsules are opaque, hard gelatine capsules, reddish-brown in colour, marked with 'NG 300' in black ink.

The capsules come in blister packs of 60 and 100.

Manufacturer and product licence holder

Manufactured by Sandoz GmbH, Biochemiestr. 10, 6250 Kundl, Austria. Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

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