

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rifinah 300/150mg Coated Tablets

rifampicin - isoniazid

sanofi



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Important things you need to know about Rifinah 300/150mg Tablets

- The name of your medicine is Rifinah 300/150mg Coated Tablets (called Rifinah 300/150mg Tablets in this leaflet).
- It is very important that you take Rifinah 300/150mg Tablets 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 tablets every 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.
- Rifinah 300/150mg Tablets makes all of your body fluids an orange or red colour. Do not worry - this is normal and not harmful.
- Take Rifinah 300/150mg Tablets on an empty stomach. This means at least 30 minutes before food or 2 hours after food.
- While you are taking Rifinah 300/150mg Tablets, you should not eat matured cheeses, cured meat, some fish (like tuna, salmon and mackerel) or drink wine and beer (see 'Taking Rifinah 300/150mg Tablets with food, drink and alcohol').
- 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 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 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:

- What Rifinah 300/150mg Tablets are and what they are used for
- What you need to know before you take Rifinah 300/150mg Tablets
- How to take Rifinah 300/150mg Tablets
- Possible side effects
- How to store Rifinah 300/150mg Tablets
- Contents of the pack and other information

1. What Rifinah 300/150mg Tablets are and what they are used for



Rifinah 300/150mg Tablets contain two different medicines called rifampicin and isoniazid. They both belong to a group of medicines called anti-tuberculous drugs. They work by killing the bacteria that cause tuberculosis.

Rifinah 300/150mg Tablets are used to treat tuberculosis (also known as TB).

2. What you need to know before you take Rifinah 300/150mg Tablets



Do not take Rifinah 300/150mg Tablets if:

- You are allergic (hypersensitive) to
 - rifampicin
 - isoniazid
 - any of the other ingredients of the Rifinah 300/150mg Tablets (see section 6)

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- You have yellowing of the skin and eyes (jaundice)
- You are taking saquinavir or ritonavir for an HIV infection (see 'Other medicines and Rifinah 300/150mg Tablets' below)
- 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 Rifinah 300/150mg Tablets.



Warnings and precautions

Talk to your doctor or pharmacist before taking Rifinah 300/150mg Tablets if:

- You have a history of kidney disease
- You experience poor coordination, poor balance, change in speech, involuntary eye movements (see section 4)
- 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 have epilepsy
- You have or have ever had mental health problems (such as depression or schizophrenia)
- You feel numb or weak in your arms and legs (peripheral neuropathy)
- You have an HIV infection
- You are underweight or malnourished
- You drink alcohol every day or you are an alcoholic
- You inject yourself with drugs
- You are a black or Hispanic woman
- 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)
- You develop a rash or experience any symptoms of thrombotic microangiopathy during your treatment (see section 4)
- Your doctor has told you that your body takes a long time to get rid of some drugs (you have a slow acetylator status)
- You wear contact lenses. Taking Rifinah 300/150mg Tablets 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 Rifinah 300/150mg Tablets.



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 Rifinah 300/150mg Tablets, 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 following the start of treatment. **Stop using rifampicin and contact a doctor** if you have symptoms of liver problems (see section 4).

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 Rifinah 300/150mg Tablets.

- 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 Rifinah 300/150mg Tablets 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. If you are aged 35 years or older, you will also need to have monthly blood tests to check how your liver is working.



Other medicines and Rifinah 300/150mg Tablets

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 Rifinah 300/150mg Tablets can affect the way some other medicines work. Also, some medicines can affect the way Rifinah 300/150mg Tablets work.

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:

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

The following medicines can make Rifinah 300/150mg Tablets work less well:

- Antacids used for indigestion. Take Rifinah 300/150mg Tablets at least 1 hour before taking antacids.
- Other medicines used for TB such as P-aminosalicylic acid (PAS) and cycloserine. PAS and Rifinah 300/150mg Tablets 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 and carbamazepine
- 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 an HIV infection such as stavudine and zalcitabine
- Some medicines used for viral infections such as indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, nevirapine, daclatasvir, simeprevir, sofosbuvir and telaprevir
- Medication for the treatment of fungal infections such as caspofungin, fluconazole, itraconazole, ketoconazole
- 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 ethinylloestradiol, 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 and inflammation 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



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