

# Rifinah® 300/150mg Coated Tablets

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(rifampicin, isoniazid)

## PATIENT INFORMATION LEAFLET

### Important things you need to know about Rifinah 300/150mg/150mg Coated 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 and drink').
- 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 symptoms 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 Rifinah 300/150mg Tablets are and what they are used for
2. What you need to know before you take Rifinah 300/150mg Tablets
3. How to take Rifinah 300/150mg Tablets
4. Possible side effects
5. How to store Rifinah 300/150mg Tablets
6. 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: Contents of the pack and other information)
- 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 '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 or pharmacist before taking Rifinah 300/150mg Tablets.

#### Warnings and precautions

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

- 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
- 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.

#### 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.

#### Take special care with Rifinah 300/150mg Tablets

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.**

#### Other medicines and Rifinah 300/150mg Tablets

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 Rifinah 300/150mg Tablets can affect the way some other medicines work. Also some medicines can affect the way Rifinah 300/150mg Tablets 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 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
- 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
- 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 and inflammation 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
- 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 Rifinah 300/150mg Tablets with food and drink

Isoniazid may interact with foods containing histamine or tyramine (e.g. matured cheeses, cured meat, some fish like tuna, salmon and mackerel, wine and beer), causing symptoms including headache, sweating, flushing, fast, uneven or forceful heartbeat (palpitations), dizziness, feel lightheaded or faint (due to low blood pressure). These foods should be avoided if you are receiving isoniazid. Your doctor will be able to advise further.

##### 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.

Rifinah 300/150mg Tablets 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 Rifinah 300/150mg Tablets. 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 Rifinah 300/150mg Tablets.

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.

##### Important information about some of the ingredients of Rifinah 300/150mg Tablets

Rifinah 300/150mg Tablets contain:

- **Sunset yellow:** This is a colouring agent that may cause allergic reactions
- **Sucrose:** If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Rifinah 300/150mg Tablets
- **Sodium:** These tablets contain less than 1 mmol sodium (23 mg) per daily dose and are essentially 'sodium-free'.

### 3. HOW TO TAKE RIFINAH 300/150MG TABLETS

Always take Rifinah 300/150mg Tablets 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 the tablets every day for the whole time the doctor has told you to take them
- Do not stop and start taking the tablets. This may increase the risk of side effects and your TB will not be treated properly

#### How to take the tablets

- Take this medicine by mouth
- Swallow the tablets whole, with a drink of water
- Take at least 30 minutes before a meal or 2 hours after a meal. They are best taken at least 30 minutes before breakfast
- Take all your tablets together each day, as a single dose
- Do not give this medicine to children
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

Your doctor may ask you to take Vitamin B6 during treatment with Rifinah 300/150mg Tablets, especially if you are malnourished, elderly or a diabetic.

#### How much to take

The usual dose is:

##### Adults and the Elderly weighing more than 50kg

- Two tablets each day
- If you are elderly, your doctor may monitor your treatment more closely

##### Adults and the Elderly weighing less than 50kg

- Rifinah 150/100mg Tablets are usually prescribed

#### Children

This medicine is not recommended for use in children.

#### If you take more Rifinah 300/150mg Tablets than you should

If you take more Rifinah 300/150mg Tablets 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, light-headed, have blurred or strange visions (hallucinations) and faint or feel faint. Other signs of taking too much include 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 Rifinah 300/150mg Tablets

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 tablets.

#### Tests

Taking Rifinah 300/150mg Tablets 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 Rifinah 300/150mg Tablets.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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.
- 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. These 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

#### If you experience any of the following side effects contact your doctor as soon as possible:

- Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis, frequency not known).
- Yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems (hepatitis, may affect up to 1 in 100 people).

#### 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'
- Your fits get worse or you start to have fits
- 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
- Balance problems with dizziness (vertigo)
- Being unable to concentrate, feeling nervous, irritable or depressed
- Feeling very tired and weak or difficulty sleeping (insomnia)
- Unusual skin sensations such as feeling numb, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Short-term memory loss, anxiety, being less alert or responsive
- Blurred or distorted eyesight
- 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
- Constipation, diarrhoea, stomach discomfort or dry mouth
- Headache
- Loss of appetite (anorexia)
- Breast enlargement in men
- Increased thirst, going to the toilet more often and feeling tired. Your blood sugar may be high
- Acne
- Inflammation of the blood vessels.

#### 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 Rifinah 300/150mg Tablets.

#### 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 RIFINAH 300/150MG TABLETS

Do not use your tablets after the expiry date shown on the box. Keep your medicine in a safe place where children cannot see or reach it. Your medicine could harm them.

Do not store above 25°C. Protect from moisture.

If your doctor decides to stop your treatment return any left over medicine to the pharmacist. Only keep them if the doctor tells you to.

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

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. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Rifinah 300/150mg Tablets contain:

They contain two active ingredients. Each tablet contains 150mg of isoniazid and 300mg of rifampicin.

The tablets also contain sodium lauryl sulphate, calcium stearate, sodium carboxymethylcellulose, magnesium stearate, Avicel PH 101 (microcrystalline cellulose), acacia, gelatin, kaolin, magnesium carbonate, talc, polyvinylpyrrolidone K-30, sucrose, titanium dioxide, aerosil 200, aluminium lacquer 17% (E-110) and FDC yellow dye.

#### What Rifinah 300/150mg Tablets look like and contents of the pack

Rifinah 300/150mg Tablets are orange, smooth, shiny, capsule shaped and sugar coated tablets.

Rifinah 300/150mg Tablets are available in blister packs of 60 tablets.

#### MANUFACTURER AND PRODUCT LICENCE HOLDER

Rifinah 300/150mg Tablets are manufactured by Sanofi-aventis SpA, (Località) Valcanello, Casella Postale N46, 03012 Anagni (Frosinone), Italy. Procured from within the EU and Repackaged by Product Licence holder P.I.E. Pharma Ltd, 207 Kenton Road, Harrow, Middlesex HA3 0HD.

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