Rifinah® 300/150mg Film-coated Tablets

Rifampicin 300mg

Isoniazid 150mg

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 gets serious, or if you notice any side effect not listed in this leaflet,

please tell your doctor or pharmacist.

In this leaflet:

1. WHAT RIFINAH IS AND WHAT IT IS USED FOR

Rifinah 300/150mg Film-Coated Tablets is one of a group of medicines used to treat tuberculosis (also known as TB) of the lung and other mycobacterial infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RIFINAH

Do not take Rifinah if:

- You are allergic (hypersensitive) to the active ingredients (isoniazid or rifampicin) or to 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).

- You are taking medicine called lurasidone for schizophrenia and bipolar disorders (see 'Taking other medicines' section below).

-You are taking cabotegravir, fostemsavir and lenacapavir for viral infections like HIV as rifampicin may reduce the blood levels of these medicines.

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.

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 Rifinah

Tell your doctor or pharmacist if:

- You have a history of lung inflammation (interstitial lung disease/pneumonitis)

- You have liver or severe kidney problems.

- You notice any of the symptoms related to cerebellar syndrome described in section 4- Possible side effects. This syndrome has been reported mainly in patients with chronic kidney disease. Your Healthcare professional may reduce the dose or ask you to stop the treatment.

- You have a problem with bleeding or tendency to bruise easily.

- You are taking other antibiotics at the same time.

- You have epilepsy.

- You feel numb or weak in your arms and legs (peripheral neuropathy).

- You have HIV infection.

- You drink alcohol every day or you are an alcoholic.

- You are a black or Hispanic woman.

- You have a rare blood problem called 'porphyria'.

- Your doctor has told you that your body takes a long time to get rid of some drugs (you have a slow acetylator status).

- Rifinah may produce a discolouration (yelllow, orange, red, brown) of the teeth, urine, sweat, sputum and tears. If you wear contact lenses- please note that Rifinah may permanently stain soft contact lenses.

- You have severe skin reactions 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 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.

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.

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 Rifinah can affect the way some other medicines work. Also some medicines can affect the way Rifinah works.

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 Rifinah work less well:

• Antacids used for indigestion. Take Rifinah at least 1 hour before taking antacids

• Other medicines used for TB such as P-aminosalicyclic acid (PAS). PAS and Rifinah 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.

• Medicines 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 and carbamazepine.

• Some medicines used for depression such as nortriptyline.

• Lurasidone for schizophrenia and bipolar disorders, as rifampicin may reduce the blood levels of lurasidone.

Medicines for infections and the immune system

• Some medicines used for viral infections such as indinavir, efavirenz, ritonavir, saquinavir, zidovudine, cabotegravir, fostemsavir, lenacapavir.

• Medicines used to treat Hepatitis C such as daclatasvir, simeprevir, sofosbuvir, and telaprevir. Concurrent use of treatment of antiviral hepatitis C drugs and rifampicin should be avoided.

• Medicines used for the treatment of fungal infections such as caspofungin, fluconazole, itraconazole, ketoconazole.

• 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 and inflammation 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.

Taking Rifinah with food and drink

The tablets should be taken either 30 minutes before a meal or 2 hours after a meal. Foods containing tyramine (e.g. cheese, red wine) and histamine (e.g. skipjack, tuna or other tropical fish) should be avoided while you are taking Rifinah Tablets.

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 Rifinah and to continue using this form of contraception for two weeks after finishing your course of treatment. This is because Rifinah 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 taking this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Rifinah

The tablets contain 0.18g of sucrose in each tablet which could be harmful if you suffer from hereditary fructose intolerance, glucose-galactose malabsorption syndrome or sucrose-isomaltase deficiency.

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

3. HOW TO TAKE RIFINAH

Your doctor or pharmacist will tell you how many tablets to take. The usual adult daily dose is 2 tablets. You should usually take all the day's tablets at the same time each day and only stop taking them if your doctor tells you to. In elderly patients, your doctor may monitor your dose more closely, especially if you show signs of liver dysfunction.

If you take more Rifinah than you should

If you take more Rifinah 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 Rifinah

If you forget to take your tablets, take them 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 tablets.

If you stop taking Rifinah

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

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Rifinah 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.

• 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).

• 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.

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

• Severe extensive skin damage (separation of the epidermis and superficial mucous membranes) (toxic epidermal necrolysis, TEN).

• Please report immediately to your doctor if you experience 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.

• A drug reaction that causes rash, fever inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome).

• Skin blistering, red/purple rash, fever headache, cough and joint pain (Stevens-Johnson syndrome, SJS).

• Large areas of red, swollen skin with small pus-filled elevations (acute generalized exanthematous pustulosis, AGEP)

• 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’.

• Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis, frequency not known)

• Seizures.

• Severe bleeding.

- 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.

• Cerebellar syndrome which includes: poor coordination of movements, poor balance, change in speech, involuntary eye movements.

Tell your doctor as soon as possible if you have any of the following side effects:

• Inflammation of the blood vessels

• 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).

• 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.

• Tooth discolouration (which may be permanent).

• Enlarged breast tissue in males (a condition known as gynecomastia).

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 or being more sensitive to sunlight.

• Irregular periods.

• Diarrhoea or stomach discomfort.

• Acne.

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

In Ireland: HPRA Pharmacovigilance Website: www.hpra.ie

In Malta: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

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

5. HOW TO STORE RIFINAH

Do not use your tablets after the expiry date shown on the blister 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 in order to protect from moisture. Do not store above 25°C. 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 contains

The tablets contain two active substances. Each coated tablet contains 300mg of rifampicin and 150mg of isoniazid. The tablets also contain: Tablet core: sodium laurilsulfate, calcium stearate, carmellose sodium, magnesium stearate, microcrystalline cellulose. Tablet coat: acacia, gelatin, kaolin (heavy), magnesium carbonate light, talc, titanium dioxide (E171), silica, colloidal anhydrous, povidone, yellow A1 lake (E110), sucrose. Tablet polish: carnauba wax.

What Rifinah looks like and contents of the pack

The film-coated tablets are orange, smooth, shiny and capsule-shaped. Each pack contains 56 tablets.

Marketing Authorisation Holder and Manufacturer

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Ireland:

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