

## **Rifater® 50mg/300mg/120mg Tablets**

*Isoniazid 50mg - Pyrazinamide 300mg - Rifampicin 120mg*  
*Sanofi Logo*

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

### **1. What Rifater is and what it is used for**

Rifater is one of a group of medicines used to treat tuberculosis (also known as TB) of the lung.

### **2. What you need to know before you take Rifater**

#### **Do not take Rifater if:**

- You are allergic (hypersensitive) to:
  - isoniazid
  - rifampicin
  - pyrazinamide
  - any of the other ingredients (see Section 6 Further information). Signs of an allergic reaction include: 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 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).

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.

Do not take if any of the above apply to you.

If you are not sure, talk to your doctor, nurse or pharmacist before taking Rifater.

## **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 Rifater**

#### **Tell your doctor or pharmacist if:**

- You have a history of lung inflammation (interstitial lung disease/pneumonitis)
- You have liver or 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 or have ever had gout (pain or swelling in the joints).
- You are coughing up blood.
- You have epilepsy.
- You have diabetes. Your diabetes may become more difficult to control while taking this medicine.
- You have a problem with bleeding or tendency to bruise easily
- You are taking other antibiotics at the same time
- You feel numb or weak in your arms and legs (peripheral neuropathy).
- You have an 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).
- Rifater may produce a discolouration (yellow, orange, red, brown) of the teeth, urine, sweat, sputum and tears. If you wear contact lenses please note that Rifater 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 Rifater Tablets.

## **Blood Tests**

Your doctor will need to check your blood before you are given 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.

## **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 Rifater can affect the way some other medicines work. Also some medicines can affect the way Rifater works.

## **In particular, do not take this medicine, and 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 Rifater Tablets work less well:**

- Antacids used for indigestion. Take Rifater Tablets at least 1 hour before taking antacids.
- Other medicines used for TB such as P-aminosalicylic acid (PAS). PAS and Rifater Tablets 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.
- Medicines use to treat Hepatitis C such as daclatasvir, simeprevir, sofosbuvir, and telaprevir.

Concurrent use of treatment of antiviral hepatitis C drugs and Rifater 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 and gestrinone.
- Levothyroxine (thyroid hormone) used for thyroid problems.
- Irinotecan - used for cancer.

### **Pain, 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 Rifater Tablets with food and drink**

You should swallow your tablets whole with water, but not with food. 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 Rifater 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 Rifater and to continue using this form of contraception for two weeks after finishing your course of treatment. This is because Rifater

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 Rifater Tablets**

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

### **Rifater contains sodium**

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

## **3. How to take Rifater**

Your doctor or pharmacist will tell you how many tablets to take.

### **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 the tablets on an empty stomach, at least 30 minutes before a meal or 2 hours after a meal.
- 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 Rifater Tablets, especially if you are malnourished, elderly or diabetic.

### **How much to take:**

The usual adult daily dose is:

### **Adults and elderly**

Between 3 and 6 tablets each day. The amount depends on your body weight. If you are elderly your doctor may monitor your treatment more closely.

### **Children**

This medicine is not recommended for use in children.

**If you take more Rifater than you should**

If you take more Rifater 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.

**If you forget to take Rifater**

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 Rifater**

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, Rifater 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, may affect up to 1 in 1,000 people).
- A drug reaction that causes rash, fever inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome, may affect up to 1 in 1,000 people).
- 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.
- 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).
- Your stomach ulcer gets worse.
- Severe bleeding
- 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.

**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.
- Increased sensitivity of your skin to sunlight and ultraviolet light (photosensitivity)
- 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.
- Balance problems with dizziness (vertigo).

- 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.
- Enlarged breasts in men (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.
- Painful, red, swollen joints.
- Pain or discomfort when passing urine.
- Irregular periods.
- Constipation, diarrhoea, stomach discomfort or dry mouth.
- Increased thirst, going to the toilet more often and feeling tired. Your blood sugar may be high.

Other side effects you should discuss with your doctor:

You notice a discolouration (yellow, brown, orange or red colour) in your teeth (which may be permanent), urine, sweat, phlegm (sputum), saliva or tears. The colour may permanently stain soft contact lenses.

**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 HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie) By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Rifater**

Do not store your tablets above 25°C. Keep them in the strips in which they are packed. Do not use Rifater after the expiry date which is stated 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.

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 Rifater contains**

The tablets contain three active substances. Each tablet contains 50mg of isoniazid, 300mg of pyrazinamide and 120mg of rifampicin. The tablets also contain povidone, carmellose sodium, sodium laurilsulfate, calcium stearate, sucrose, acacia gum, talc, light magnesium

carbonate, kaolin, colloidal silicon dioxide, aluminium hydroxide dried gel and colours titanium dioxide (E171) and iron oxide (E172).

**What Rifater looks like and contents of the pack**

The tablets are light pink, smooth, shiny, round and sugar coated. Each pack contains 100 tablets.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:**

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