

Safety update: CCDS v2-8 (resubmission)

## PATIENT INFORMATION LEAFLET (Clean) 18 August 2022

### SCHEDULING STATUS:

S4

RIFINAH® 150/75 Film-coated tablets

RIFINAH® 300 FC Film-coated tablets

rifampicin and isoniazid

Sugar free

### Read all of this leaflet carefully before you start taking RIFINAH

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.
- RIFINAH has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

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

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## 1. What RIFINAH is and what it is used for

The active substances in RIFINAH are rifampicin and isoniazid.

RIFINAH film-coated tablets are used to treat tuberculosis (also known as TB) of the lung as well as tuberculosis outside the lung.

## 2. What you need to know before you use RIFINAH

### Do not take RIFINAH if:

- you know you are hypersensitive (allergic) to rifampicin or other rifamycins, isoniazid, or any of the ingredients of RIFINAH tablets (see section 6). (Signs of an allergic reaction include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue (see section 4)).
- you have acute porphyria (hereditary blood condition causing your skin to blister or darken the colour of your urine)
- you have jaundice (yellowing of the skin and eyes)
- you develop or have previously developed thrombocytopenia purpura (easy or excessive bruising and superficial bleeding into the skin causing a rash of pinpoint sized reddish-purple spots) after using RIFINAH or rifampicin
- you are taking both saquinavir and ritonavir for treatment of HIV infection
- you have a rare blood problem called porphyria.

## Warnings and precautions

Tell your doctor or healthcare provider before taking RIFINAH, if:

- you have problems with your liver
- you have kidney problems

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- you are or may become pregnant or are breast feeding (see: Pregnancy and breastfeeding)
- you feel numb or weak in your arms and legs (peripheral neuropathy)
- you have diabetes. Your diabetes may become more difficult to control while taking RIFINAH.
- you have a problem with bleeding or a tendency to bruise easily
- you are taking other antibiotics at the same time, e.g. cefazolin (see section 2 - Other medicine and RIFINAH)
- you are underweight or malnourished
- you wear contact lenses. Taking RIFINAH may permanently stain soft contact lenses (see “Rifinah contains Rifampicin” below and section 4).
- if you are using oral contraceptives or anticoagulants (medicines to thin your blood e.g. warfarin) (see section 2 - Other medicine and RIFINAH)
- you are aged 65 years or older.

Take special care with RIFINAH:

- It is very important that you take RIFINAH exactly as your doctor has told you. There is a chance of you developing a severe and dangerous allergic reaction if you do not take RIFINAH each day as you are told. You must keep taking RIFINAH until your doctor tells you to stop.
- The active ingredients in RIFINAH interact with many other medicines, therefore you should not take any other medicines without medical advice.
- While taking RIFINAH you must visit your doctor at least once a month. Tell your doctor if you experience any problems with your RIFINAH treatment.
- Blood tests: Your doctor will need to check your blood before you take RIFINAH. This will help your doctor know if any changes happen to your blood after taking RIFINAH. You may

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also need to have regular blood tests to check how your liver is working especially if you are older than 35 years of age, suffer from chronic liver disease or drink alcohol regularly.

- RIFINAH may stain your teeth and body fluids (urine, sweat, sputum and tears) a yellow, orange, red or brown colour. Do not worry - this is normal and not harmful (see section 4). The red colour in tears may last for some time after you have stopped having RIFINAH, while the colour of the teeth may be permanent.

Tell your doctor or health care provider immediately if you note any of the following during treatment with RIFINAH:

- 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 Tablets. Treatment with Rifinah must be discontinued immediately:
  - SJS/TEN can appear initially as reddish target spots or circular patches often with central blisters on the trunk. Also, ulcers of the 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.

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- liver problems such as hepatitis (inflamed liver). Symptoms include yellowing of the skin, gums or eyes (jaundice), or tiredness, weakness, general feeling of illness (malaise), loss of appetite, nausea or vomiting.
- itching, weakness, loss of appetite, nausea, vomiting, abdominal pain, yellowing of eyes or skin or dark urine. These may be due to cholestasis (when bile cannot flow from the liver).

## Children

RIFINAH tablets are unsuitable for children under 12 years.

## Other medicine and RIFINAH

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). RIFINAH can affect the way some other medicines work. Also, some medicines can affect the way RIFINAH works.

*In particular, do not take RIFINAH, and tell your doctor, if you are taking:*

- saquinavir and ritonavir (used for HIV infection). See section 2 - Do not take RIFINAH, above.

*The following medicines can make RIFINAH work less well:*

- antacids used for indigestion, opioid painkillers (e.g. codeine) or the antifungal medicine ketoconazole. Take RIFINAH at least 1 hour before taking antacids.
- other medicines used for TB such as P-aminosalicylic acid (PAS).

*Tell your doctor if you are taking any of the following medicines:*

Heart and blood medicines:

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- medicines for high blood pressure, calcium channel blockers (e.g. diltiazem, nifedipine, verapamil), losartan, enalapril
- medicines for heart problems or to control your heartbeat (e.g. disopyramide, quinidine, flecainide, propafenone) or other heart medicines such as beta-blockers (e.g. propranolol) or cardiac glycosides (e.g. digitoxin, digoxin)
- medicines used to thin the blood such as warfarin or clopidogrel
- medicines used to lower cholesterol (clofibrate or statins such as atorvastatin, 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) including benzodiazepines and related medicine (e.g. diazepam, zopiclone, zolpidem, triazolam)
- medicines to help you sleep (barbiturates, e.g. hexobarbital)
- medicines used for epilepsy or seizures such as phenytoin carbamazepine, ethosuximide and primidone
- some medicines used for depression such as nortriptyline.

Medicines for infections and the immune system:

- some medicines used for viral infections such as zidovudine, saquinavir, indinavir, efavirenz, atazanavir, lopinavir and nevirapine
- medicines used for fungal infections (e.g. fluconazole, itraconazole, ketoconazole)
- medicines used for bacterial infections (e.g. chloramphenicol, clarithromycin, telithromycin, doxycycline, dapsone, ciprofloxacin, levofloxacin)
- other antituberculosis medicines (e.g. cycloserine)
- medicines used for lowering your immune system such as azathioprine, ciclosporin, sirolimus and tacrolimus

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- praziquantel - used for tapeworm infections
- atovaquone - used for pneumonia.

Hormone and cancer medicines:

- some hormone medicines (estrogen, progestogens or systemic hormones, e.g. ethinyloestradiol, levonorgestrel or dydrogesterone) used for contraception or some types of cancer
- some hormone medicines (anti-estrogens) used for breast cancer or endometriosis such as tamoxifen and toremifene
- levothyroxine (thyroid hormone) used for thyroid problems
- irinotecan - used for cancer.

Pain, inflammation and gout medicines:

- medicines used for pain (narcotic analgesics) such as codeine, morphine, fentanyl, pethidine
- corticosteroids used for inflammation such as hydrocortisone, betamethasone and prednisolone
- methadone - used for heroin withdrawal.

Other medicines:

- medicines used for diabetes (sulfonylureas such as glibenclamide, gliclazide, glipizide, glimepiride or thiazolidinediones such as pioglitazone)
- 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
- disulfiram (used in alcohol dependence)

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- other antibiotics (to treat bacterial infections), e.g. cefazolin.

Make sure to inform your doctor if you are using any of the above medicines before you start treatment with RIFINAH. Your doctor may want to adjust the dose of your medicine if needed.

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. RIFINAH may make “the Pill” less effective. If you have any questions or are unsure about this, talk to your doctor, pharmacist or other health care professional.

If you are using anticoagulants (medicines to thin your blood e.g. warfarin), RIFINAH may cause your blood to clot more easily. You may need more frequent monitoring of your anticoagulant dosage.

*Laboratory tests:* Taking RIFINAH may affect the results of some blood tests. In particular, tests for folate and vitamin B12. If you are going to have a blood test, it is important to tell your doctor that you are taking RIFINAH.

### **Taking RIFINAH with food, drink and alcohol:**

While you are being treated with RIFINAH, do not have cheese, red wine or some fish (e.g. skipjack tuna or other tropical fish) as this may lead to symptoms such as itching of your skin, rapid or pounding heart, sweating, flushing, headache and low blood pressure (fainting).

Using alcohol while you are being treated with RIFINAH can increase your risk of developing liver disease or problems.

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Your daily dose of RIFINAH should be taken preferably on an empty stomach (at least 30 minutes before a meal or 2 hours after a meal) to ensure rapid and complete absorption.

### **Pregnancy and breastfeeding and fertility:**

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or health care professional for advice before taking RIFINAH.

The safety of RIFINAH in pregnant and breastfeeding women has not been established.

### **Driving and using machinery:**

You may feel dizzy or faint, have problems with vision or other side effects that could affect your ability to drive while taking RIFINAH. If this happens, do not drive or use any tools or machines.

### **3. How to take RIFINAH**

Do not share RIFINAH prescribed for you with any other person.

Always take RIFINAH and other medicines exactly as your doctor has instructed you take. You should check with your doctor or pharmacist if you are unsure.

Your doctor or pharmacist will tell you how many tablets to take. The usual adult daily dose is 2 or 3 tablets of the RIFINAH 150/75 or 2 tablets of the RIFINAH 300 FC, depending on your weight.

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. It is essential to take the tablets every day for 5 consecutive days per week and not to stop and start them as this could cause important side-effects. The treatment may last up to four months and must not be interrupted.

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If you are older than 35 years or elderly, your doctor may monitor your dose more closely, for signs of liver dysfunction.

RIFINAH tablets are unsuitable for children under 12 years.

Your daily dose of RIFINAH should be taken preferably on an empty stomach at least 30 minutes before a meal or 2 hours after a meal to ensure rapid and complete absorption.

If you are taking antacids (used for indigestion) while you are being treated with RIFINAH, take RIFINAH at least 1 hour before taking antacids.

### **If you take more RIFINAH than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

### **If you forget to take RIFINAH**

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.

### **Effect when treatment with RIFINAH is stopped**

You must take the tablets each 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 (see: Take special care with RIFINAH) and your infection will not be treated properly.

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#### **4. Possible side effects**

RIFINAH can have side effects.

Not all the side effects reported for RIFINAH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RIFINAH, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking RIFINAH and tell your doctor or pharmacist immediately or go to the casualty department at your nearest hospital:

*Frequency unknown:*

- you have signs of a serious allergic reaction which can include swelling of the lips, face, throat or tongue, hands, feet, ankles, or throat which may cause difficulty in swallowing or breathing or cause you to collapse
- 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 (pemphigoid).
- 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, extensive skin damage such as skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (see section 2).
- widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (known as DRESS syndrome) (see section 2)

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- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis (AGEP)) (see section 2)
- blotchy red skin rash (erythema multiforme)
- you have blood in your urine or an increase or decrease in amount of urine you produce. You may also get swelling, especially in the legs, ankles or feet, but also in any area of the body. This may be caused by serious kidney problems.
- you have severe bleeding (haemorrhage)
- 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to RIFINAH. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Frequent:*

- blood disorders (e.g. thrombocytopenia) which are determined by blood tests. Signs may include bruising more easily than usual or you may have a rash of dark red spots under the skin (purpura).

*Less frequent:*

- you have a fever and yellowing of the skin or whites of the eyes, feel tired, weak or generally unwell, lose your appetite, nausea, vomiting. These may be early signs of liver problems such as hepatitis (inflamed liver).

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- blood disorders (e.g. low or abnormal number of white blood cells) which are determined by blood tests. Signs may include getting infections more easily than normal, fever, sore throat, mouth ulcers or tiredness.
- blood disorders which are determined by blood tests. Signs may include chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark coloured urine (haemolytic anaemia), or weight loss, night sweats and fever (eosinophilia).
- immune system problems with symptoms that include tiredness, joint pain and skin rashes (called lupus-like syndrome)
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)

*Frequency unknown:*

- abnormal blood clotting in your blood vessels. Signs may include bleeding from your nose, ear, gums, throat, skin or stomach, tenderness and swelling in your stomach or tar-like stools.
- 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.
- severe watery diarrhoea that will not stop and you are feeling weak and have a fever (called pseudomembranous colitis)
- flu-like symptoms including chills, fever, headache, dizziness and bone pains
- mental problems with unusual thoughts and strange visions (hallucinations)
- muscle weakness, muscle pain or bone pain
- water retention (oedema) which may cause swollen fingers, toes, or ankles or legs
- your fits get worse or you start to have fits
- vision problems such as loss of sight, blurred vision and reduced vision.

These are all serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following:

*Frequent:*

- headache
- dizziness
- feeling sick or being sick
- blood tests may show changes in the way the liver is working

*Less frequent:*

- eye irritation or disturbances in your vision
- diarrhoea
- feel lightheaded, dizzy and faint especially when you stand or sit up quickly (due to low blood pressure)
- tingling and loss of feeling (this can be prevented with the use of pyridoxine)
- skin conditions (including acne, lumpy red rash, red/purple skin discolouration (purpura), itching and skin scaling)
- fever.

*Frequency unknown:*

- inflammation in your blood vessels (vasculitis)
- loss of appetite (anorexia)
- feeling drowsy
- skin flushing
- stomach problems or discomfort
- skin rash or itching
- irregular periods
- vertigo (feeling off balance or as if your head is spinning)

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- memory problems, diarrhoea, scaly skin rash this may be due to Vitamin B3 deficiency (Pellagra)
- breast enlargement in men
- loss of feeling (numbness)
- nerve problems which can cause memory loss, movement problems (muscle weakness) or the loss of full control of bodily movements and may affect your manner of walking (ataxia)
- unusual skin sensations such as feeling numb, tingling, pricking, burning or creeping on the skin (paraesthesia)
- dry mouth
- constipation
- chronic or recurrent stomach pain
- hair loss
- a yellow, orange or red or brown discolouration of your teeth, urine, sweat, phlegm (sputum), saliva or tears. This is quite common and you need not worry. However, the red colour may permanently stain soft contact lenses. The red colour in tears may last for some time after you have stopped having RIFINAH, while the colour of the teeth may be permanent.
- blood tests may show changes in the way your kidneys are working.

If you notice any side effects not mentioned in this leaflet, please inform 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 report any side effects directly to Sanofi's Pharmacovigilance Unit at [za.drugsafety@sanofi.com](mailto:za.drugsafety@sanofi.com) (email) or 011 256 3700 (tel).

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You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**” found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

## 5. How to store RIFINAH

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place.

Do not remove tablets from the blister before ready to use.

Do not use your tablets after the expiry date shown on the container.

Return all unused medicine to your pharmacist.

## 6. Contents of the pack and other information

### What RIFINAH 150/75 and RIFINAH 300 FC contains

RIFINAH tablets contain two active ingredients:

Each RIFINAH 150/75 tablet contains 150 mg of rifampicin and 75 mg of isoniazid. Each RIFINAH 300 FC tablet contains 300 mg of rifampicin and 150 mg of isoniazid.

Other ingredients are: Polyvinylpyrrolidone, sodium lauryl sulphate, croscarmellose sodium, microcrystalline cellulose, starch, glyceryl behenate, magnesium stearate.

The film coating of RIFINAH 150/75 contains: Aluminium lake pigments (Sunset Yellow FCF, Ponceau 4R and Indigo carmine), macrogol, partly hydrolysed polyvinyl alcohol, talc, titanium dioxide, iron oxide yellow and iron oxide red.

The film coating of RIFINAH 300 FC contains: Aluminium lake pigments (Allura red AC and Sunset Yellow FCF), macrogol, partly hydrolysed polyvinyl alcohol, talc, titanium dioxide.

### What RIFINAH looks like and contents of the pack

RIFINAH 150/75: Rust brown, 9,1 mm round, biconvex, film-coated tablets.

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The tablets are packed in packs of 56 and 84 tablets in foil-foil blisters.

RIFINAH 300 FC: Warm orange, 11 mm round, biconvex, film-coated tablets.

The tablets are packed in packs of 56 tablets in foil-foil blisters.

**Holder of Certificate of Registration**

Sanofi-Aventis South Africa (Pty) Ltd.

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1685

South Africa

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**Registration numbers**

RIFINAH 150/75: A40/20.2.3/0534

RIFINAH 300 FC: A40/20.2.3/0535

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