

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Rifadin® 600mg Infusion (rifampicin)

#### Important things you need to know about Rifadin Infusion

- You must keep taking it until your doctor tells you to stop.
- If you are having any other medicines, including medicines you have bought from the pharmacy or shop, you must make sure your doctor knows
- Rifadin Infusion makes all your body fluids an orange or red colour. Do not worry - this is normal and not harmful
- 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 the rest of this leaflet carefully before you start having 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 only. Do not pass it to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

The name of your medicine is Rifadin 600mg Infusion but will be referred to as Rifadin Infusion throughout the remainder of the leaflet.

#### What is in this leaflet

- What Rifadin Infusion is and what it is used for
- What you need to know before you take Rifadin Infusion
- How Rifadin Infusion is given
- Possible side effects
- How to store Rifadin Infusion
- Contents of the pack and other information

#### 1. What Rifadin Infusion is and what it is used for

Rifadin Infusion contains a medicine called rifampicin. It belongs to a group of medicines called anti-infectives. It works by killing the bacteria that cause infections.

Rifadin Infusion is used to treat the following bacterial infections when medicines cannot be given by mouth:

- Tuberculosis (also known as TB) alongside other medicines
- Leprosy alongside other medicines
- Brucellosis alongside other medicines
- Legionnaires Diseases alongside other medicines
- Other serious bacterial infections

#### 2. What you need to know before you take Rifadin Infusion



##### Do not have Rifadin Infusion if:

- You are allergic (hypersensitive) to
  - rifampicin
  - any of the other ingredients of the Rifadin Infusion (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 Rifadin Infusion' below)
- You are currently taking any of the following medicines:
  - sofosbuvir – antiviral medicine for treatment of hepatitis C virus infections
  - cabotegravir, fostemsavir, lenacapavir – HIV medicines
  - lurasidone (medicine for schizophrenia and bipolar disorders) as rifampicin may reduce the blood levels of several medicines including the above listed.

Do not have if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before having Rifadin Infusion.



##### Warnings and precautions

##### Inform your doctor immediately while taking this medicine

- If your symptoms of tuberculosis return or get worse (see section 4).

##### Talk to your doctor, nurse or pharmacist before having Rifadin Infusion if:

- 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 feel numb or weak in your arms and legs (peripheral neuropathy)
- You are under weight or malnourished

- 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 (Please see section 4 Possible side effects)
- You develop a rash or experience any symptoms of thrombotic microangiopathy during your treatment (see section 4 Possible side effects)
- You wear contact lenses. Having Rifadin Infusion may permanently stain soft contact lenses
- The person having 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, nurse or pharmacist before having Rifadin Infusion.

##### Lung inflammation

**Inform your doctor immediately while having 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 have rifampicin, a component of Rifadin Infusion, 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 Possible side effects).

##### 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 Rifadin Infusion.

- 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 Rifadin Infusion and contact your doctor or seek medical attention immediately.**

##### 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 having this medicine. You may also need to have regular blood tests to check how your liver is working.



##### Other medicines and Rifadin Infusion

Tell your doctor, nurse 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 Rifadin Infusion can affect the way some other medicines work. Also, some medicines can affect the way Rifadin Infusion work.

**Tell your doctor, nurse or pharmacist if you are pregnant and planning or required to undergo pregnancy termination** using mifepristone.

**In particular, do not have 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 Rifadin Infusion work less well:

- Antacids used for indigestion. Have Rifadin Infusion at least 1 hour before taking antacids
- Other medicines used for TB such as P-aminosalicyclic acid (PAS). PAS and Rifadin Infusion should be taken at least 8 hours apart

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

##### Heart and blood medicines

- Medicines for high blood pressure
- Medicines for heart problems or to control your heart beat
- 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
- 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 viral infections such as cabotegravir, fostemsavir, lenacapavir, 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 ethinyloestradiol, 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, inflammation and gout 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

##### Pregnancy and breast-feeding

Talk to your doctor before having this medicine if you are pregnant, plan to get pregnant or think you are pregnant.

Rifadin Infusion 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 having Rifadin Infusion. If you have any questions or are unsure about this talk to your doctor, nurse or pharmacist.

You should not breast-feed if you are having Rifadin Infusion. 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, nurse 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 having this medicine. If this happens, do not drive or use any tools or machines.

##### Rifadin Infusion contains sodium

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

**The following information is intended for healthcare professionals only:**

**Practical information on preparation and administration of Rifadin 600mg Infusion (see also Section 3).**

##### Posology and method of administration

Treatment with Rifadin for Infusion should include concomitant use of other appropriate anti-bacterials to prevent the emergence of resistant strains of causative organism.

##### Tuberculosis:

Adults: A single daily administration of 600mg given by intravenous infusion over 2 - 3 hours has been found to be effective and well tolerated for adult patients. Serum concentrations following this dosage regimen are similar to those obtained after 600mg by mouth.

Children: The usual paediatric regimen is a single daily dose of up to 20mg/kg bodyweight; the total daily dose should not normally exceed 600mg.

Leprosy: The recommended daily dose is 10 mg/kg.

Usual daily dose:

Patients weighing less than 50 kg - 450 mg.

Patients weighing 50 kg or more - 600 mg.

Alternatively, 600 mg doses of rifampicin may be given once per month. In the treatment of leprosy, rifampicin should always be used in conjunction with at least one other anti-leprosy drug.

##### Brucellosis, Legionnaires Disease or serious staphylococcal infections:

Adults: The recommended daily dose is 600 - 1200mg given in 2 - 4 divided doses, together with another antibacterial agent with similar properties to prevent the emergence of resistant strains.

Impaired liver function: A daily dose of 8mg/kg should not be exceeded in patients with impaired liver function.

Use in the elderly: In elderly patients, the renal excretion of rifampicin is decreased proportionally with physiological decrease of renal function; due to compensatory increase of liver excretion, the serum terminal half-life is similar to that of younger patients. However, as increased blood levels have been noted in one study of rifampicin in elderly patients, caution should be exercised in using rifampicin in such patients, especially if there is evidence of liver function impairment.

When patients are able to accept oral medication, they should be transferred to Rifadin Capsules or Syrup (for further information on these products see their data sheets).

##### Overdose

Human Experience

##### Signs and Symptoms:

Nausea, vomiting, abdominal pain, pruritus, headache and increasing lethargy will probably occur within a short time after acute ingestion; unconsciousness may occur when there is severe hepatic disease. Transient increases in liver enzymes and/or bilirubin may occur. Brownish-red or orange colouration of the skin, urine, sweat, saliva, tears and faeces will occur, and its intensity is proportional to the amount ingested. Facial or periorbital oedema has also been reported in paediatric patients. Hypotension, sinus tachycardia, ventricular arrhythmias, seizures and cardiac arrest were reported in some fatal cases.

The minimum acute lethal or toxic dose is not well established. However, non fatal acute overdoses in adults have been reported with doses ranging from 9 - 12 g rifampicin. Fatal acute overdoses in adults have been reported with doses ranging from 14-60 g. Alcohol or a history of alcohol abuse was involved in some of the fatal and non fatal reports. Nonfatal overdoses in paediatric patients ages 1 - 4 years old of 100 mg/kg for one to two doses have been reported.

##### Management:

Intensive supportive measures should be instituted, and individual symptoms treated as they arise. Since nausea and vomiting are likely to be present, gastric lavage is probably preferable to induction of emesis. Following evacuation of the gastric contents, the instillation of activated charcoal slurry into the stomach may help absorb any remaining drug from the gastrointestinal tract. Antiemetic medication may be required to control severe nausea and vomiting. Active diuresis (with measured intake and output) will help promote excretion of the drug. Haemodialysis may be of value in some patients.

##### Incompatibilities

Compatibilities: up to 6 hours with Saline Solution and up to 8 hours with Glucose 5%. Incompatibilities: Perfudex, Sodium Bicarbonate 5%, Sodium Lactate 0.167M, Ringer Acetate with Glucose.

### Shelf life

Unopened vial of lyophilisate: 36 months

Unopened ampoule of solvent: 60 months

Shelf life after dilution or reconstitution:

Up to 30 hours with Water for injections (10ml WFI)

Up to 8 hours with Water for injections (10ml WFI) and then diluted in glucose 5% solution for infusion

Up to 6 hours with Water for injections (10ml WFI) and then diluted in sodium chloride 0.9% solution for infusion

### Special precautions for storage

Do not store above 25°C.

### 3. How Rifadin Infusion is given

Rifadin Infusion is given by a doctor or nurse. This is because it needs to be given as a slow drip into a vein (infusion).

#### How much is given

If you are not sure why you are being given Rifadin Infusion or have any questions about how much Rifadin Infusion is being given to you, speak to your doctor or nurse.

#### Tuberculosis (TB)

- The usual dose is:
  - Adults: A single daily dose of 600mg given over 2 - 3 hours
  - Children: Up to 20mg per kilogram of body weight each day. The maximum dose is 600mg each day

#### Leprosy

- Your doctor may prescribe a monthly or daily dose
  - Patients weighing less than 50kg: A single daily dose of 450mg
  - Patients weighing more than 50kg: A single daily dose of 600mg

#### Brucellosis, Legionnaires Disease or other serious bacterial infections

- The amount you are given will depend on how severe your infection is
  - Adults: 600mg - 1200mg each day. The dose is given in 2 - 4 divided doses.

#### Elderly patients

Your doctor may need to monitor you more closely

#### People with Liver problems

You should not be given any more than 8mg per kilogram of body weight each day

#### If you are given more Rifadin Infusion than you should

Your doctor will carefully calculate how much Rifadin Infusion you should get. Therefore, it is unlikely your doctor or nurse will give you too much of this medicine. But, if you think that you have been given too much or too little Rifadin Infusion, tell your doctor or nurse.

You may feel sick (nausea), be sick (vomiting), have stomach pain, itching or a headache. You may also feel tired, sleepy, dizzy or light-headed.

Other signs of having too much includes swelling of the face, eyes or eyelids, slurring of speech, difficulty breathing, fast heart beat, uneven heart beats, fits and heart attack.

#### If you miss a dose of Rifadin Infusion

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you think you may have missed a dose, then talk to your doctor or nurse.

#### Tests

Having Rifadin Infusion 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 having Rifadin Infusion.

### 4. Possible side effects

Like all medicines, Rifadin Infusion can cause side effects, although not everybody gets them.

#### Tell a nurse or doctor 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
- Nausea (feeling sick) or vomiting (being sick), fever, feeling tired, loss of appetite (anorexia), dark-coloured urine, light-coloured faeces, yellowing of the skin or whites of the eyes, itching, rash or upper stomach pain. These symptoms may be signs of liver injury.
- 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 high blood levels of uric acid.
- You have severe bleeding (haemorrhage)

- 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.
- You have chills, tiredness, unusually pale skin colour, shortness of breath, fast heart beat 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
- New or sudden worsening of shortness of breath and wheezing, possibly with a cough or fever. These could be symptoms of inflammation of the lungs (interstitial lung disease/pneumonitis).
- You get confused, sleepy, cold clammy skin, shallow or difficult breathing, a racing heart beat 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
- 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'
- Flu-like symptoms including chills, fever, headache, dizziness and bone pains
- Inflammation of the liver – yellowing of the skin and white part of eyes, increase in the blood level of liver enzymes
- Blood clots in small blood vessels (thrombotic microangiopathy) – Symptoms may include increased bruising, bleeding, fever, extreme weakness, headache, dizziness or light-headedness. Your doctor may find changes in your blood and the function of your kidneys.

#### 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
- Being unable to concentrate, feeling nervous, irritable or depressed
- Feeling very tired and weak or difficulty sleeping (insomnia)
- Short-term memory loss, anxiety, being less alert or responsive
- 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 (nausea) or being sick (vomiting)

#### Tell your doctor, nurse or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Skin flushing or itching
- Irregular periods
- Loss of appetite (anorexia)
- Headache
- Diarrhoea or stomach discomfort
- Pain, redness or swelling at the site of injection

#### Other side effects you should discuss with your doctor if you are concerned about them

You notice a discolouration (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 Rifadin Infusion.

#### 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 Rifadin Infusion

**Keep out of the sight and reach of children.**

Do not use Rifadin Infusion after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Rifadin Infusion contains:

- Once the solvent and powder have been mixed, each 10ml solution contains 600mg of the active ingredient, rifampicin.
- The other ingredients are sodium sulfoxylate formaldehyde, sodium hydroxide.
- Each solvent ampoule contains 10ml water for injections.

#### What Rifadin Infusion look like and contents of the pack

Rifadin Infusion is presented as a 20ml clear glass vial sealed with rubber stopper and aluminium/plastic flip-off cap (colour coded blue) containing a red to brick-red coloured powder and a 10ml clear glass ampoule containing a colourless solvent.

Pack size – 1 vial with 1 ampoule of solvent.

Manufactured by: Sanofi S.p.A., Via Valcanello, 4, 03012 Anagni (FR), Italy. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Limited, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Road, Worsley, Manchester, M28 3PT.

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Is this leaflet hard to see or read?  
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