

Rifadin[®] INJECTION

(rif-ar-din)

Rifampicin (rif-am-pee-cin)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Rifadin.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being administered Rifadin against the benefits he/she expects it will have for you.

If you have any concerns about being administered this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Rifadin is used for

Rifadin is an antibiotic that is used in combination with other medicines to treat tuberculosis, also known as TB. TB is a bacterial infection, which mainly affects the lungs but it can also spread to other organs in the body.

Rifadin is also used to treat leprosy, a skin condition that has many forms.

Rifadin is also used to prevent certain diseases occurring where you may be in contact with, or have had contact with, a person known to have the disease or is known to be able to pass it on to others. Examples of such diseases are meningitis, a serious infectious disease (an inflammation

of the membranes that cover the brain and spinal cord), affecting children and young adults, and pneumonia, conjunctivitis and meningitis caused by *Haemophilus influenzae*, a bacterium in the respiratory tract.

This medicine is available only with a doctor's prescription.

Before you are given it

When you must not be given it

Do not use Rifadin if:

You have an allergy to Rifadin (rifampicin) or any other rifamycin antibiotics or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing or swallowing, and swelling of the face, lips, tongue and throat.

You have jaundice (yellowing of the eyes and skin).

You are taking combination saquinavir/ritonavir medications.

You are breast-feeding or planning to breastfeed.

Rifadin passes into breast milk and there is a possibility your baby may be affected.

The packaging is torn or shows signs of tampering.

The expiry date (exp) printed on the pack has passed.

If you use this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start using Rifadin, talk to your doctor.

Before you are given it

Tell your doctor if:

You have any type of liver disease.

You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

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

You are taking other antibiotics at the same time.

You have diabetes.

You are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of using Rifadin during pregnancy.

You are breast-feeding or plan to breast-feed.

Rifadin should not be used while breast-feeding.

If you have not told your doctor about any of the above, tell them before you are given Rifadin.

Urine, faeces, saliva, sputum, sweat, tears and teeth may be coloured red-orange, yellow or brown by Rifadin. Soft contact lenses may be permanently stained.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some drugs should not be taken with Rifadin. These include:

- The combination of saquinavir and ritonavir, antiviral agents used to treat acquired immune deficiency syndrome (AIDS) and human immunodeficiency virus (HIV) infections.
- Halothane, a general anaesthetic (a sleep inducing drug)
- Daclatasvir, simeprevir, sofosbuvir and telaprevir, antiviral agents used to treat Hepatitis C
- Cephazolin and other cephalosporin antibiotics used to treat infection.

Some medicines and Rifadin may interfere with each other. These include:

- Atovaquone, used to treat a respiratory infection in Acquired Immune Deficiency Syndrome (AIDS)
- Ketoconazole, used for fungal infections
- Enalapril, used to treat high blood pressure and heart problems
- Isoniazid and p-aminosalicylic acid (PAS), used for TB (tuberculosis).

Rifadin may reduce the effectiveness of a wide variety of medicines or they may affect how well Rifadin works. These include certain medicines used for:

- Decreasing the clotting of the blood
- Controlling and preventing seizures
- Heart disease and high blood pressure
- Breast cancer treatment or prevention
- Sedation

- Bacterial infections
- Fungal infections
- Inflammatory conditions
- Contraception
- High blood cholesterol
- Diabetes
- TB and leprosy
- Malaria
- Rejection of transplanted organs
- Thyroid deficiency states
- Pain
- Nocturnal cramps
- Breathing difficulties
- Anxiety or depression
- Treatment of certain mental illnesses
- Treatment of HIV (Human Immunodeficiency Virus) infections.
- Nausea and vomiting

Your doctor may have more information on medicines to be careful with or to avoid while receiving Rifadin.

How it is given

Rifadin is diluted and given by intravenous infusion.

Rifadin must only be given by a doctor or nurse.

Your doctor will decide what dose and for how long you will receive Rifadin.

While you are being given it

Things you must do

If you develop itching with swelling or skin rash or difficulty breathing, or if you turn yellow while you are receiving Rifadin do not receive any more Rifadin and tell your doctor immediately.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Rifadin has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore white mouth or tongue while being treated with or soon after stopping Rifadin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Rifadin allows fungi to grow and the above symptoms to occur. Rifadin does not work against fungi.

If you become pregnant while you are receiving Rifadin tell your doctor.

If you are using oral contraceptives you should change to alternative methods of birth control while you are receiving Rifadin.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are receiving Rifadin.

If you have to have any blood or urine tests tell your doctor you are being given Rifadin.

Rifadin may affect the results of some blood and urine tests.

Tell all the doctors, dentists and pharmacists who are treating you that you are being treated with Rifadin.

Side effects

Check with your doctor as soon as possible if you have any problems while being treated with Rifadin, even if you do not think the problems are connected with the

medicine or are not listed in this leaflet.

Like other medicines, Rifadin can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Yellow discolouration of skin or eyes
- Heartburn, loss of appetite, nausea, vomiting, upset stomach, abdominal discomfort, wind, cramps or diarrhoea
- Drowsiness, fatigue, inability to concentrate, confusion, or mental problems
- Poor coordination, muscle weakness, pain in the fingers or toes, or numbness
- Oral thrush - white, furry, sore tongue and mouth
- Vaginal thrush - sore and itchy vagina and/or discharge
- Conjunctivitis or visual disturbances
- Menstrual disturbances.

Tell your doctor immediately if you notice any of the following:

- Severe red and/or itchy skin, blisters or pimples, bleeding, peeling or bruising of the skin
- Swelling of the face, lips, tongue or throat which may cause difficulty in breathing or swallowing
- Shortness of breath and wheezing
- Blood in the urine or any other urination disturbances
- Severe bleeding or bruising more easily than normal
- Fever, chills, headache or dizziness
- Bone pain.

Some people may get other side effects while being treated with Rifadin.

Some of these side effects (for example changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Urine, faeces, saliva, sputum, sweat, tears and teeth may be coloured red-orange, yellow or brown by Rifadin. Soft contact lenses may be permanently stained.

After being given it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Rifadin:

- Severe abdominal cramps or stomach cramps
- Watery and severe diarrhoea, which may also be bloody
- Fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel, which may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhoea medicine without first checking with your doctor.

After giving it

Storage

Store Rifadin in the pharmacy or on the ward. Keep the powder for IV infusion in a cool dry place where the temperature stays below 25°C.

Use Rifadin immediately after it has been made up into a solution.

Product Description

What It Looks Like

Red to brick-red powder for injection, in a vial. Supplied with a colourless 10 mL diluent ampoule.

Ingredients

Active Ingredient:

Rifadin 600 mg - 600 mg active per vial

Inactive Ingredients:

- sodium formaldehyde sulphonylate 10 mg
- sodium hydroxide q.s. to pH = 8.5

Diluent contains water for injections q.s. to 10 mL.

Manufacturer/Sponsor

Rifadin is supplied in Australia by:
sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Rifadin is supplied in New Zealand by:
sanofi-aventis new zealand limited
Level 8, 56 Cawley Street
Ellerslie
Auckland

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