

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### RIFAMOR

300 mg, capsule, hard

RIFAMPICIN

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What Rifamor is and what it is used for
2. Before you take Rifamor
3. How to take Rifamor
4. Possible side effects
5. How to store Rifamor
6. Further information

#### 1. WHAT RIFAMOR IS AND WHAT IT IS USED FOR

RIFAMOR contains an active substance that is called rifampicin. It belongs to a group of medicines, called anti-infective medicines. They act by killing the bacteria that cause the infection.

RIFAMOR is used in the treatment of the following bacterial infections:

- Tuberculosis (TB), along with other medicines
- Leprosy (chronic infectious disease that affects peripheral nerves, skin, upper respiratory tract, eyes and mucous membranes of the nose, caused by the bacterium *Mycobacterium leprae*) with other medicines
- Brucellosis (a disease that is transmitted from animals to man, by direct contact or through infected milk and dairy products, caused by Gram negative bacteria *Brucella*) with other medicines
- Legionnaire's disease (inflammation of the lungs caused by bacteria called *Legionella pneumoniae*) with other medicines
- Haemophilus influenza, Gram positive bacteria - bacillus, which may give many infectious diseases, such as pneumonia and sinusitis, conjunctivitis, meningitis, inflammation of bones, joints, soft tissue
- Other more difficult bacterial infection

RIFAMOR can also be used to stop further progression following infection;

- meningitis, inflammation of the meninges (the membrane lining the brain and spinal cord), which can be caused by bacteria, viruses and other infectious agents.

## 2. BEFORE YOU TAKE RIFAMOR

### **Do not take Rifamor:**

- If you are allergic (hypersensitive) to rifampicin
- Some of the ingredients of the medicine RIFAMOR (see 6: Further Information)
- The signs of an allergic reaction include: rash, problems with swallowing or breathing, swelling of the lips, face, throat and tongue
- If you have a yellow discoloration of the skin and eyes (jaundice)
- If you are taking saquinavir and ritonavir, due to HIV infection (see 'Taking other medicines')
- Do not take the medicine, if any of the above applies to you. If you are unsure ask your doctor or pharmacist before you start taking the medicine RIFAMOR.

### **Take special care with Rifamor:**

- You have liver problems
- You have any problems with the kidneys, and if you are taking more than 600mg of RIFAMOR a day
- You have diabetes. While taking this medicine, your diabetes may become more difficult to control
- You feel numbness or weakness in the hands and feet (peripheral neuropathy)
- You are underweight or malnourished
- You have rare disease of blood, which is called porphyria
- Wear contact lenses. Taking medication RIFAMOR may permanently color the your soft contact lenses
- You have 65 years or more

### **Blood tests**

Before you start to take the medicine RIFAMOR, your doctor will have to control your blood. This will help your doctor in the event that, after taking the medicine, there are changes in your blood work. It will also be necessary to regularly control the blood, to check liver function.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Do not take medicine RIFAMOR if you are taking:

- Saquinavir and ritonavir, used for treatment of HIV infection

The following medicines may reduce the operation of the medicine RIFAMOR:

- Antacids, which are used for digestive problems. RIFAMOR take at least 1 hour before taking antacids
- Other medicines, which are used in the treatment of TB, such as p-aminosalicylic acid (PAS). Between takings of these medicines there should not be less than 8 hours.

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

Medicines for heart and blood

- Medicines for high blood pressure
- Medicines for heart problems or to control heart rhythm
- Medicines used to thin the blood, such as warfarin
- The medicines used for reducing cholesterol levels in the blood
- Diuretics as eplerenone

Medicines for mental health, epilepsy and motor neurons

- Medicines for disorder of thought, known as " antipsychotics " such as haloperidol
- Tranquilizers or to reduce tension (hypnotics, anxiolytics)
- Medicines that help you sleep (barbiturates)
- Medicines used for epilepsy, such as phenytoin
- Some medicines used for depression, as amitripty
- Riluzole • - used for motor neuron disease

#### Medicines for infection and for imunisistem

- Some medicines used for viral infection as indinavir, efavirenz, amprenavir, nelfinavir, atazanavir,
- Lopinavir and nevirapin
- Medicines used for fungal infections
- Medicines used for bacterial infections (antibiotics)
- Medicines used to decrease an immune response such as cyclosporine, sirolimus and tacrolimus
- Praziquantel -which is used for tapeworm infection
- Atovaquone - used for pneumonia

#### Hormonal medicines and medicines for treatment of cancer

- Some hormonal medicines (estrogen, systemic hormones, progestogens) used for birth control or some types of cancer, as ethinyloestradiol, levonorgestrel and dydrogesterone
- Some hormonal medicines (anti-estrogen) that are used for the treatment of breast carcinoma and endometriosis, as tamoxifen, toremifene and gestrinone
- Some medicines used to treat cancer (cytostatic) as imatinib
- levothyroxine (thyroid hormone) that is used for the problem with the thyroid gland
- Irinotecan - used to treat kracinoma

#### Painkillers, anti-inflammatory and medicines for gout

- Non-steroidal anti-inflammatory medicines (NSAIDs) as etoricoxib, aspirin and indomethacin
- Medicines used painkillers like codeine, morphine, fentanyl and pethidine
- Corticosteroids used for inflammation as hydrocortisone, betamethasone and prednisone
- Methadone - which is used for withdrawal from heroin

#### Other medicines

- Medicines for diabetes
- Medicines used for muscle relaxation prior to surgery (anesthesia) as halothane
- Some medicines used for nausea or vomiting as ondansetron and aprepitant
- Quinine - a medicine for malaria
- theophylline - medicine for wheezing or difficulty breathing

### ***Taking food and drink with RIFAMOR***

Rifamor should be taken on an empty stomach, which means at least 30 minutes before eating or 2 hours after a meal.

If RIFAMOR taken with food and medicines listed below, can you experience headaches, sweating, flushing, rapid, uneven and enhanced heart rate (palpitations), dizziness, dizziness, fainting (due to low blood pressure).

While taking the medicine RIFAMOR do not take:

- Cheese
- Tuna or other tropical fish
- Red wine

### ***Pregnancy and breastfeeding***

Talk to your doctor before you start taking this medicine if you are pregnant, planning to become pregnant or think you are pregnant.

RIFAMOR may reduce the effect of the contraceptive pill. This means that you should change your method of contraception. While taking RIFAMOR, instead of pill use another reliable method of barrier contraception, such as condoms or 'spiral' '. If you have any questions or concerns, please consult your doctor or pharmacist.

If you are taking RIFAMOR, you should not breast-feed, because small amounts of the medicine can pass into breast milk. If you are breastfeeding or planning to breastfeed, talk to your doctor or pharmacist before you start taking any medication.

Before taking any medicine, consult your doctor or pharmacist.

### **Other warnings**

While taking this medicine, you may feel dizzy or faint. You may have a problem with your eyesight or other adverse reactions, which may affect your ability to operate motor vehicles. If this happens, do not drive, use tools or machines.

## **3. HOW TO TAKE RIFAMOR**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Continue taking the medicine

- You need to take the capsules every day for as long as your doctor has told you to take this medicine.
- Do not interrupt and start taking the capsules. This can increase the risk of side effects, and your infection will not be treated as they should.
- How to take the capsules
- Swallow the capsules whole with water.
- Take your medicine at least 30 minutes before meals or 2 hours after a meal.
- If you think the effect of the medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

### **How much to take**

How much of the medicine will be prescribed depends on your age and the type of illness you have.

#### **Tuberculosis (TB):**

- RIFAMOR should be administered with at least one TB medicine
- The usual doses are:
- Patients who have less than 50 kg: 450 mg once a day.
- Patients who have more than 50 kg: 600 mg once a day.

#### **Leprosy:**

- RIFAMOR should be administered with at least one medicine for leprosy.
- Your doctor may prescribe a monthly or daily dose. The usual dose is:
- Patients who have less than 50 kg: 450 mg once a day.
- Patients who have more than 50 kg: once daily 600 mg.

#### **Brucellosis, Legionnaires' disease or other serious infections:**

- RIFAMOR medicine should not be taken together with another antibiotic.
- The amount of medication that the doctor prescribes will depend on how severe your infection is:
- Adults: 600 mg to 1200 mg daily. The dose is administered in 2 to 4 divided daily doses.

#### **Stopping the development of meningitis:**

- The usual dose:
- Adults: 600 mg twice daily for two days.

#### **Stopping the development of Haemophilus influenzae:**

- All members of the household must be treated according to the instructions of doctors.
- The usual dose is:

- Adults: 20 mg per kilogram body weight daily for four days. More than 600 mg should not be given.

### **Elderly**

The doctor may need to monitor you more carefully.

### **People who have liver problems**

You should not receive more than 8 mg per kilogram body weight per day.

### **Tests**

Taking RIFAMOR can affect blood tests, particularly tests for folate, vitamin B12 and liver function.

If you plan on doing blood tests, it is important to tell your doctor that you are taking medication RIFAMOR.

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

Contact your doctor. If possible, bring a capsule, this instruction or packaging with you to show the doctor what you have taken. You may feel nauseous, vomit; have stomach pains, itching or headache. You can also feel tired, sleepy, have dizziness. Other signs of taking more medicines than you should are swelling of the face, eyes or eyelids, speech problems, difficulty breathing, rapid breathing, seizures and heart attacks.

### **If you forget to take Rifamor**

If you miss a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking RIFAMOR**

Do not stop taking RIFAMOR unless your doctor advises you to do so.

If you have any further questions about the application of Rifamor, talk to your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Rifamor may cause side effects.

Stop taking the medicine, if you notice any of the following serious side effects:

- You have an allergic reaction. The signs may include: rash, swelling or difficulty breathing, wheezing, swelling of the lips, face, throat or tongue.
- You have a fever and yellow discoloration of the skin or the white part of the eyes, feel tired, weak, or generally feel bad, you have loss of appetite (anorexia), nausea, vomiting. These may be signs of liver problems.
- If at any part of the skin emerge blisters, if the skin is peeling, bleeding, starts to moisturize. This includes the lips, eyes, mouth, nose, genitals, hands or feet. You can have a serious skin problem.
- If you bruise out easier than before. If you have a painful rash or dark red spots under the skin, which do not disappear when you press them (purpura). This may be due to serious blood problems.
- If you have chills, fatigue, unusually pale skin color, shortness of breath, rapid heart rate or dark discoloration of urine. These could be signs of severe type of anemia.
- If you have blood in the urine, increase or decrease the amount of urine you produce. You can swell, especially the legs, ankles or feet. This may be due to serious kidney problems.
- You have sudden severe headache. This may be a sign of bleeding in the brain.
- Shortness of breath and wheezing.
- If you are confused, sleepy, you have a cold, sticky skin, shallow or labored breathing, rapid heart rate or your skin is paler than usual, this may be a sign of shock.
- If you get an infection more easily than normal. Signs include fever, dry, sore throat, or sores on the oral cavity. This may be due to a reduced number of white blood cells.
- If you have bleeding from the nose, ears, gums, throat, stomach, skin. tenderness and bloating of the stomach, purple spots on the skin, and black tarry stool.

Immediately contact your doctor if you notice any of the following serious side effects:

- Mental problems, if you have unusual thoughts and see strange things (hallucinations).

- Severe watery diarrhea that does not stop, nausea and fever. This may be something called pseudomembranous colitis.
- Flu-like symptoms, including chills, fever, headache, dizziness, pain in the bones.

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

- Water retention (edema), which may cause swelling of the face, abdomen, arms and legs.
- Muscle weakness or pain, or loss of muscle reflexes.
- Vertigo, dizziness, fainting, especially when sitting down or getting up sharply (due to low blood pressure).
- Swollen fingers and legs or swollen ankles.
- Hair loss, loss of body hair.
- Cannot concentrate, you're nervous, irritable or depressed.
- Feeling very tired, weak or have trouble sleeping (insomnia).
- Short-term memory loss, anxiety, if you you lowered the level of attention and if you have slow reactions.
- Reduction of muscle or other body tissues.
- The loss in body weight, night sweats and fever. These can be signs of blood condition called eosinophilia.
- Nausea or vomiting.

Tell your doctor or pharmacist if any of the following side effects worsen or last longer than a few days:

- Redness of the skin or itching
- Irregular menstruation
- Diarrhea or stomach upset
- Loss of appetite (anorexia)
- Headache.

Other side effects, for which should consult your doctor if you are concerned

- If you notice an orange or reddish color of urine, sweat, mucus, saliva or tears. This is very common and nothing to worry about. However, the color red can permanently stain contact lenses.

Red staining of tears may last some time after discontinuation of the medicine RIFAMOR.

Blood tests

- Blood tests may indicate changes in liver function.

If you notice any side effect, talk to your doctor or pharmacist.

## 5. HOW TO STORE RIFAMOR

Keep out of reach and sight of children.

Store the medicine at a temperature below 30° C in a dry place and protected from light.

Rifamor must not be used after the expiry date stated on the packaging.

Shelf life: 4 years.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### **What does Rifamor contain?**

#### **Active substance:**

1 capsule, hard contains 300 mg of rifampicin

#### **The other ingredients:**

The content of powder in the capsule:

starch, corn;  
magnesium stearate.

The content of empty capsules: gelatin;

titanium dioxide;  
indigo carmine (E132);  
erythrosine (E127).

#### **Pharmaceutical form:**

Capsule, hard

### **What Rifamor looks like and contents of the pack**

The hard, opaque gelatin capsules N ° 1, the red body and red cap filled with powder dark red.

2 blisters PVC / AL / PVC, with 8 capsules, hard (16 capsules, hard) in a cardboard box.

#### **Regime of dispensing**

The medicine is issued on prescription.

#### **Manufacturer**

Galenika ad  
Batajnički drum bb  
11080 Belgrade, Serbia