

# RIFASYNT CAPSULES

Rifampicin (150mg, 300mg)

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## What RIFASYNT is used for

“RIFASYNT” is used as:

- Lung infection (tuberculosis)
- Prevention for inflammation of brain and spinal cord (meningococcal meningitis)
- Infection of skin, mucous membrane, nerve (Leprosy)
- Other infections eg. Brucellosis, Legionnaires
- Haemophilus influenza (an infection caused by bacteria)

The doctor will tell you exactly why you are receiving the product.

## How RIFASYNT works

RIFASYNT is an antibiotic used to treat several types of bacterial infections. It works by stopping the production of bacteria.

## Before you use RIFASYNT

### -When you must not use it

You should not take RIFASYNT if you have:

- Allergies to the rifampicin or to any of the ingredients of RIFASYNT mentioned.
- Jaundice
- Been receiving saquinavir/indinavir therapy
- Liver impairment

### -Before you start to use it

Rifampicin might affect the liver function, therefore it is given to you after investigation and supervision by doctor. Rifampicin may produce discoloration of the teeth, urine and tears, you should be alert if you are wearing soft contact lenses as it might permanently stain your lenses.

## Pregnancy and Breastfeeding

If you are pregnant, or you think you are pregnant or plan to get pregnant, consult doctor before you take RIFASYNT. Do not take this medicine if you are breast-feeding, since the medicine may pass into breast milk, unless under the advice of your doctor.

## -Taking other medicines

Before taking this medicine tell your doctor or pharmacist if you are taking:

- Antiviral eg. saquinavir,ritonavir, simeprevir
- Anesthetic eg. halothane
- Antibiotics eg. Isoniazid, cefazolin, cephalosporins, fluoroquinolones, p-aminosalicylic acid, atovaquone
- Antiarrhythmics eg. Disopyramide, mexiletine, quinidine, propafenone, tocainide
- Antiepileptics eg. Phenytoin
- Hormone antagonist eg. Tamoxifen, toremifene, gestrone
- Antipsychotics eg. Haloperidol, aripiprazole
- Anticoagulants eg. coumarins
- Antifungals eg. Fluconazole, itraconazole, ketoconazole
- Barbiturates
- Beta-blockers eg. Bisoprolol, propranolol
- Anxiolytics and hypnotics eg. Diazepam, benzodiazepines
- Calcium channel blockers eg. Diltiazem, nifedipine
- Corticosteroids
- Anticholesterol agent eg. Clofibrate
- Systemic hormonal contraceptives eg. Estrogens, progestogens
- Antidiabetic eg. Chlorpropamide, tolbutamide
- Immunosuppressive agents eg. Ciclosporin, sirolimus
- Anticancer agent eg. Irinotecan
- Thyroid hormone eg. Levothyroxine
- Antihypertensive agent eg. Losartan, enalapril
- Analgesics eg. Methadone, narcotic analgesics, morphine
- Antiworm eg. Praziquantel
- Antimalaria agent eg. Quinine
- Nerve medicine eg. Riluzole

- Selective 5-HT3 receptor antagonists eg. Ondansetron
- Statins metabolised by CYP3A4 eg. Simvastatin
- Theophylline
- Tricyclic antidepressants eg. Amitriptyline, nortriptyline
- Cytotoxics eg. Imatinib
- Diuretics eg. Eplerenone
- Antacid

You should tell your doctor about all the other medicines you are taking, including those medicines you buy without a prescription.

## How to use RIFASYNT

### -How much to use

#### *Tuberculosis:*

*Adults:* 8-12mg/kg. Usual dose for weight less than 50kg is 450mg; for weight 50kg or more is 600mg

*Children:* 10-20mg/kg. Not exceed 600mg.

#### *Prevention of meningococcal meningitis:*

*Adult:* 600mg twice daily for 2 days

*Children 1-12 years:* 10mg/kg twice daily for 2 days

*Children 3months-1years:* 5mg/kg twice daily for 2 days.

*Leprosy:* 600mg once per month. Alternatively, single daily dose is 10mg/kg. Usual dose for weight less than 50kg is 450mg; for weight 50kg or more is 600mg.

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

*Adults:* 600-1200mg in 2 to 4 divided doses

#### *Prevention of Haemophilus influenzae:*

*Adult:* Any members of your family exposed to H. influenzae B disease when your household contains a child 4 years of age or younger, the doctor might recommend you dose of 20mg/kg once daily (max 600mg daily) for 4 days. *Neonates (1month):* 10mg/kg for 4 days.

*Impaired liver function:* should not exceed daily dose 8mg/kg.

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## Elderly:

Your doctor might reduce your dose as accordance to your liver condition.

## -When to use it

Rifampicin should preferably be taken at least 30minutes before a meal or 2 hours after meal.

## -How long to use it

Your doctor will tell you how long you should take this medicine. It is important not to stop taking this medicine until your doctor advises you to.

## -If you forget to use it

Do not worry. If you do forget to take a dose, leave out the missed dose and take the next dose on time. Never take two doses together.

## -If you use too much (overdose)

If you take too much doses than you should, contact your pharmacist or doctor straight away. If you cannot, go to your nearest hospital. Always take the packet of medicine with you, so they know what you have taken.

Symptoms of overdose are nausea, vomiting, abdominal pain, headache and increasing tiredness.

## **While you are using it**

### -Things you must do

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### -Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not give RIFASYNT to anyone else, even if they have the same symptoms or condition as you.

### -Things to be careful of

#### Driving and operating machinery

It is unknown whether rifampicin will affect your concentration. If you feel drowsy, stop driving or operate machinery.

## **Side effects**

As with all medicines, during the treatment with RIFASYNT you may experience some side effects. The side effects of RIFASYNT are:

- Clotting of blood (Disseminated intravascular coagulation)
- Abdominal discomfort, feeling sick, vomiting
- Scaling of skin (exfoliate dermatitis)
- Disturbance of hormone production (adrenal insufficiency)
- Mental disorder (psychoses)
- Fever, chills, headache, dizziness
- Shortness of breath and wheezing
- Disturbances of menstrual cycle
- Liver failure
- Low blood platlet count (thrombocytopenia)

This is not a complete list of side-effects. If you notice any of these side effects or any other, contact with your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## **Storage and Disposal of RIFASYNT**

### -Storage

- RIFASYNT should be stored in a dry place away from the light and at a temperature below 30°C in original package
- Keep out of reach of children.

### -Disposal

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.

Do not use the medicine after the expiry date. This is written on the carton. It is also embossed on each blister of capsules.

## **Product Description**

### -What it looks like

RIFASYNT 150mg capsules are hard gelatin capsules, with scarlet colour, size 2. RIFASYNT 300mg capsules are hard gelatin capsules, with scarlet colour, size 1

### -Ingredients

- Active ingredient  
RIFASYNT contain rifampicin as active substance. The available strengths are 150mg and 300mg.
- Inactive ingredient  
The inactive ingredients for RIFASYNT 150mg and 300mg are lactose monohydrate, croscarmellose sodium and magnesium stearate. The capsule shells contain gelatin, erythrosine (E127), indigo carmine (E132) and titanium dioxide (E171).

### -MAL number:

RIFASYNT	150MG
MAL19860789AZ	
RIFASYNT	300MG
MAL19860825AZ	

## **Manufacturer**

Medochemie Ltd, 1-10  
Constantinoupoleos Street, 3011  
Limassol, Cyprus

## **Product Registration Holder**

Komedic Sdn Bhd, 4 Jalan PJS 11/14,  
Bandar Sunway, 46150 Petaling Jaya

## **Date of revision**

23/06/2020

## **Serial Number**

NPRA (R4/1)100420/00060