

**Package Leaflet: Information for the user**  
**Mycobutin®150mg capsules**  
rifabutin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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

**1. What Mycobutin is and what it is used for**

Mycobutin contains the active substance rifabutin, which is an antibiotic. It is used to treat infections caused by germs (bacteria) called mycobacteria. These are bacteria which cannot be destroyed with usual antibiotics.

- One of the most common mycobacterial infections is *Mycobacterium tuberculosis*. Mycobutin can be used in combination with other antibiotics for the treatment of tuberculosis of the lung.
- Mycobutin can also be used to treat other mycobacterial infections such as *Mycobacterium avium intracellulare* (MAI, also known as MAC) or *Mycobacterium xenopi*.
- People who are unable to fight infection (such as those with HIV) are more likely to be infected with mycobacteria; especially MAC. Mycobutin can be given (on its own) to people with HIV disease when the number of CD4 cells (part of the immune system) falls below 75 per microlitre of blood. This will help to stop them from developing MAC infections.

You should consult your doctor if you are unsure why you have been given Mycobutin.

**2. What you need to know before you take Mycobutin**

**Do not take Mycobutin**

- if you are allergic (hypersensitive) to rifabutin or other drugs to treat tuberculosis or any of the other ingredients of this medicine (listed in section 6)
- if you are being treated with medicines containing rilpivirine that are administered as prolonged-release suspension for injection
- if you are pregnant or breast-feeding

- if the medicine has been prescribed for a child under 12 years

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Mycobutin.

Stop taking Mycobutin and contact your doctor immediately if you have any of the following symptoms (drug reaction with eosinophilia and systemic symptoms (DRESS)):

- skin rash, fever
- swollen lymph nodes and change in blood count

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 anti-tuberculosis medicines.

- SJS/TEN can appear initially as reddish target-like 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.

If a severe allergic reaction or SCAR occurs during treatment with Mycobutin, the medicinal product should be discontinued and appropriate measures taken.

Medicines are not always suitable for everyone. Your doctor needs to know before you take Mycobutin if you suffer from or have suffered in the past from problems with your liver or kidneys.

It is common for Mycobutin to colour your urine (water) red/orange, you may also experience colouring of the skin and other body fluids. These are nothing to worry about. It can also colour soft contact lenses.

Your doctor will carry out tests to check that you do not have active tuberculosis or another mycobacterial disease. You may also have regular eye examinations if you are taking Mycobutin with other medicines to treat an infection.

You may need to take Mycobutin for the rest of your life, to prevent you from getting MAC infection.

### **Other medicines and Mycobutin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you have bought for yourself.

Some medicines can affect the way Mycobutin works when they are taken at the same time, or Mycobutin itself can reduce the effectiveness of other medicines taken at the same time. You should therefore inform your doctor if you are taking any of the following medicines:

- medicines to treat diabetes
- painkillers (e.g. aspirin)
- narcotics (including methadone)
- anticoagulants (blood thinners) such as warfarin
- corticosteroids (to treat inflammation or allergy) such as prednisolone
- ciclosporin or tacrolimus (to suppress the immune system)
- quinidine or digitalis (but not digoxin) (for heart conditions)
- dapsone (to treat skin infections or pneumonia)
- phenytoin (to treat epilepsy)
- anti-fungals (especially fluconazole, itraconazole, posaconazole, voriconazole, ketoconazole or miconazole)
- anti-virals to treat HIV/AIDS (especially atazanavir/ritonavir, bictegravir, doravirine, darunavir/ritonavir, dolutegravir, elvitegravir/cobicistat, etravirine/ritonavir, indinavir, rilpivirine (for oral use eg. tablets), saquinavir, ritonavir or amprenavir, fosamprenavir/ritonavir, lopinavir/ritonavir, tipranavir/ritonavir)
- clarithromycin (an antibiotic)
- sofosbuvir (to treat hepatitis C)
- bedaquiline (to treat tuberculosis).

When taking Mycobutin, **oral contraceptives (the pill)** may not prevent pregnancy. You are advised to use other forms of birth control.

### **Pregnancy, breast-feeding and fertility**

You should not take Mycobutin if you are pregnant or breast-feeding.

If you think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Mycobutin is not expected to affect your ability to drive or use any tools or machinery.

### **Information about the ingredients**

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

## **3. How to take Mycobutin**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The capsules should be taken by mouth, once a day.

Mycobutin is usually given in combination with other antibiotics for treating mycobacterial infections.

The number of capsules depends upon the condition you are being treated for.

Mycobutin can be taken before or after food and drinks.

The usual doses are:

### **Tuberculosis:**

1 to 3 capsules once a day

**Treatment of other mycobacterial infections:**

3 to 4 capsules once a day, though your doctor may prescribe a lower dose if you are taking certain other drugs

**When used to prevent MAI/MAC Infection:**

2 capsules once a day

If you are taking Mycobutin to treat an infection you may not feel better for 2 to 3 weeks. You should continue taking your capsules unless your doctor tells you otherwise.

**If you take more Mycobutin than you should**

If you accidentally take too much Mycobutin contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there are any Mycobutin capsules left or not.

**If you forget to take Mycobutin**

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. **Do not take a double dose to make up for a forgotten dose.**

**If you stop taking Mycobutin**

Do not stop taking Mycobutin unless your doctor tells you to as your infection could return.

If you have any further questions on how to take Mycobutin, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Tell your doctor immediately** if you experience any of the following serious symptoms after taking this medicine.

- Sudden wheeziness, difficulty in breathing, pain in the chest, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- Diarrhoea, stomach pain, blood in stool and/or increase in body temperature may occur during, or after completing treatment with antibiotics and could be a sign of serious bowel inflammation.
- Anaphylactic shock, as seen with other antibiotics of the same class.
- Frequent and/or severe infections, mouth and/or throat ulcers, unusual or unexplained bruising or bleeding, small (pin-point) red spots on the skin and/or in the mouth, unusually pale skin, feeling weak (symptoms of blood disorders).
- A drug reaction with symptoms such as fever, skin rash, changed blood count, enlarged lymph nodes and serious hypersensitivity reaction.
- Serious skin rashes including Stevens-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. Stop using Mycobutin if you develop these symptoms and contact your doctor or seek medical attention immediately. 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). Stop using Mycobutin if you develop these symptoms and contact your doctor or seek medical attention immediately. 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 generalised exanthematous pustulosis). Stop using Mycobutin if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

### **Other side effects**

Common side effects (may affect up to 1 in 10 people)

- nausea (feeling sick)
- fever/high temperature
- skin rash
- muscle pain

Uncommon side effects (may affect up to 1 in 100 people)

- pain or redness in the eye, cloudiness or loss of vision
- yellowing of the skin and eyes, itchy skin, dark urine (symptoms of jaundice)
- vomiting (being sick)
- aching joints
- skin discolouration

Additional side effects have also been reported including flu-like symptoms, chest pressure or pain with shortness of breath, inflammation of the liver (hepatitis) and haemolysis (loss of red blood cells), the frequency is unknown.

Your doctor will need to take regular blood tests while you are on Mycobutin as it may affect the level of white and red blood cells, platelets (which help the blood clot) and substances produced by the liver known as enzymes. This will make sure your blood and liver are working properly.

### **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 Mycobutin**

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

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 Mycobutin contains**

Each Mycobutin capsule contains 150mg of the active ingredient rifabutin.

The other ingredients are microcrystalline cellulose, sodium laurylsulfate, magnesium stearate, gelatin and silica gel.

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

Mycobutin capsules are opaque, red-brown hard gelatin capsules presented in blister packs of 30 capsules.

### **Marketing Authorisation Holder**

Pfizer Limited  
Ramsgate Road  
Sandwich  
Kent  
CT13 9NJ  
United Kingdom

### **Company Contact Address:**

For further information on your medicine contact Medical Information at Pfizer Limited, Walton Oaks, Dorking Road Tadworth, Surrey, KT20 7NS. Tel: 01304 616161.

### **Manufacturer**

Pfizer Italia S.r.l.  
Marino del Tronto  
Ascoli Piceno  
Italy.

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