

PACKAGE LEAFLET: INFORMATION FOR THE USER
Mycobutin^(R) 150 mg Hard 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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. 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 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.

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

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Mycobutin

Your doctor will discuss your condition with you before you start taking your capsules. Your treatment with Mycobutin will be combined with other anti-mycobacterial drugs treatments. Tell your doctor if you are taking other rifamycins (drugs used to treat bacteria).

Do not take Mycobutin

- if you are allergic (hypersensitive) to rifabutin, rifamycins, other drugs to treat tuberculosis or any of the other ingredients of Mycobutin listed in section 6
- if you have porphyria, a rare blood disorder.

Warnings and precautions

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

- if you suffer from, or have suffered in the past from, problems with your liver or kidneys, tell your doctor before you take Mycobutin
- it may colour urine, skin or other body fluids red/orange
- it may permanently discolour soft contact lenses
- your doctor will carry out regular blood tests during your treatment with Mycobutin. They may also check that you do not have active tuberculosis or another mycobacterial disease.
- you may need regular eye examinations if you are taking Mycobutin with other medicines.

Tell your doctor if you have had any antibiotics in the last two months to help your doctor decide if this medicine is suitable for you. This is because Mycobutin may cause you to have severe diarrhoea or inflammation of the colon.

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, 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 including those for severe pain such as codeine, morphine, oxycodone, pethidine or tramadol
- 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 (especially indinavir, saquinavir or ritonavir, amprenavir, fosamprenavir/ritonavir, lopinavir/ritonavir, tipranavir/ritonavir)
- clarithromycin (an antibiotic).

Oral contraceptives

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Mycobutin with food and drink

This medicine is not affected by food and can be taken with or without meals.

Pregnancy, breast-feeding and fertility

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

If you are pregnant or breast-feeding, 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 machinery.

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 tuberculosis.

The usual dose is one to three capsules once a day.

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

Use in children

Mycobutin is not recommended for use in children.

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 Mycobutin can cause side-effects, although not everybody gets them.

Tell your doctor immediately or go to the nearest hospital casualty department if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- Sudden wheeziness, difficulty in breathing, pain in the chest, swelling of eyelids, face or lips, rash or itching (symptoms of an allergic reaction)
- Yellowing of the skin and eyes, itchy skin, dark urine (symptoms of jaundice)

- Severe watery diarrhoea that will not stop. You may also feel weak and have a fever (symptoms of pseudomembranous colitis)
- Frequent and/or severe infections (especially sore throats), unexplained fever, 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, shortness of breath, feeling weak (symptoms of blood disorders).
- pain or redness in the eye, cloudiness or loss of vision (which is reversible)
- flu-like symptoms and/or aching joints or muscles.

The most common side effects when you take Mycobutin are:

- nausea (feeling sick), vomiting
- pain in the chest
- fever/high temperature
- skin rash

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 as they may increase. 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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.
Do not store above 30 °C.

Do not use Mycobutin after the expiry date which is stamped on the pack. 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 laurilsulphate, magnesium stearate, gelatin, red iron oxide, titanium oxide 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. The capsule cap is marked MYCOBUTIN and capsule body is marked Pharmacia&Upjohn.

Marketing Authorisation Holder and Manufacturer

Pfizer Healthcare Ireland
9 Riverwalk, National Digital Park
Citywest Business Campus
Dublin 24, Ireland

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

Company contact address:

For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland , 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.
Telephone 1800 633 363

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