

# MYCOBUTIN® CAPSULES

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking Mycobutin?

Mycobutin contains the active ingredient rifabutin. Mycobutin is taken in combination with other medicines to treat mycobacterial infections e.g. tuberculosis (TB) or Mycobacteria avium-intracellulare complex (MAC). It may also be taken to prevent infections in patients with HIV disease. For more information, see Section [1. Why am I taking Mycobutin?](#) in the full CMI.

### 2. What should I know before I take Mycobutin?

Do not take if you have ever had an allergic reaction to Mycobutin or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any problems with your liver or kidneys, any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take Mycobutin?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Mycobutin and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take Mycobutin?

Mycobutin capsules should be swallowed whole once a day. They may be taken at any time and do not need to be taken with food. Follow the instructions provided by your doctor. Do not stop taking Mycobutin unless your doctor tells you to, even if you feel better. More instructions can be found in Section [4. How do I take Mycobutin?](#) in the full CMI.

### 5. What should I know while taking Mycobutin?

#### Things you should do

- Tell your doctor immediately if you become pregnant while you are taking Mycobutin.
- If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several

	<p>weeks after Mycobutin has been stopped.</p> <ul style="list-style-type: none"> <li>● Remind any doctor or dentist you visit that you are taking Mycobutin.</li> <li>● Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.</li> <li>● Tell your doctor immediately if you have any pain, redness or blurry vision.</li> <li>● Tell your doctor immediately if you have a moderate or severe skin rash or blisters often with flu-like symptoms</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop taking this medicine without advice from your doctor first.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools</li> </ul>

	until you know how Mycobutin affects you.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• No information available.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store it in a cool dry place away from moisture, heat or sunlight.</li> <li>• Keep your capsules in their original packaging, including outer carton, until it is time to take them. If you take the medicine out of the pack, it may not keep well.</li> </ul>

For more information, see Section [5. What should I know while taking Mycobutin?](#) in the full CMI.

## 6. Are there any side effects?

- Side effects may include nausea and vomiting, pain in joints and muscles, red-orange coloured urine and possibly discoloured skin or body secretions. More serious side effects include allergic reactions (shortness of breath, chest pain or rashes that may or may not be itchy, coughing and wheezing), diarrhoea, even after Mycobutin is stopped, skin rash with flu like symptoms, eye pain, redness or, blurry vision, unexpected bleeding or bruising and fever. For more information, including what to do if you have any side

effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Mycobutin<sup>®</sup> Capsules

Active ingredient(s): *Rifabutin*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking Mycobutin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Mycobutin.**

**Where to find information in this leaflet:**

- [1. Why am I taking Mycobutin?](#)
- [2. What should I know before I take Mycobutin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Mycobutin?](#)
- [5. What should I know while taking Mycobutin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking Mycobutin?

**Mycobutin contains the active ingredient rifabutin.** Mycobutin is an antibiotic, an agent taken to kill certain types of bacteria, known as mycobacteria.

Mycobutin is taken in combination with other medicines to treat mycobacterial infections e.g. tuberculosis (TB) or Mycobacteria avium-intracellulare complex (MAC). It

may also be taken to prevent infections in patients with HIV disease.

Your doctor, however, may prescribe Mycobutin for another purpose. Ask your doctor if you have any questions about why Mycobutin has been prescribed for you.

Mycobutin can only be obtained on prescription from a doctor.

## **2. What should I know before I take Mycobutin?**

### **Warnings**

#### **Do not take Mycobutin if:**

1. You are allergic to rifabutin, other rifamycin antibiotics (e.g. rifampicin), or any of the ingredients listed at the end of this leaflet.
2. Always check the ingredients to make sure you can take this medicine.
3. You are taking treatments that include ritonavir or prolonged-release rilpivirine injections
4. The packaging is torn or shows signs of tampering
5. The expiry date printed on the pack has passed.

Do not give Mycobutin to children.

## **Check with your doctor if you:**

- have any other medical conditions
- have or have had problems with your liver or kidneys
- take any medicines for any other condition
- are or may become pregnant during the time in which you are taking Mycobutin.
- are breastfeeding or intend to breast-feed

Your doctor may need to adjust your dose or your treatment in these situations.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Oral contraceptives may be affected by Mycobutin. Discuss with your doctor about using a different means of birth control during treatment with Mycobutin.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with Mycobutin and affect how it works.**

- treatments for HIV, e.g. saquinavir, indinavir, ritonavir, amprenavir, fosamprenavir, lopinavir, nevirapine, bicitgravir, doravirine, rilpivirine, elvitegravir/cobicistat
- anti-hepatitis C virus treatments, e.g. sofosbuvir
- anti-tuberculosis treatments, e.g. bedaquiline
- other antibiotics, e.g. clarithromycin, erythromycin, chloramphenicol, trimethoprim, atovaquone
- anti-fungal treatments, e.g. fluconazole, itraconazole, ketoconazole, posaconazole, voriconazole
- oral contraceptives, e.g. ethinylestradiol/norethisterone
- oestrogens, e.g. in hormone replacement therapy (HRT)
- heart medicines
- medicines taken orally for diabetes
- epilepsy medicines, e.g. phenytoin
- sedatives, sleeping pills or medicines to treat anxiety
- corticosteroids (used to treat inflammatory diseases, such as skin disorders, asthma or rheumatoid arthritis, or as replacement therapy in adrenal disorders)
- tacrolimus (used to prevent organ transplant rejection)

- methadone or other opiates, such as morphine (used for severe pain or to treat drug dependence)
- cisapride (used to treat heartburn or stomach ulcers)
- warfarin (used after a heart attack or to treat blood clotting disorders)

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mycobutin.**

## **4. How do I take Mycobutin?**

### **How much to take**

- The dose of Mycobutin depends on the infection for which you are being treated and the other medicines you are taking.
- The usual dose of Mycobutin will be 2 to 4 capsules per day (1-2 capsules per day for newly diagnosed pulmonary tuberculosis patients), but this may not always apply. Your doctor will decide your dose.
- Follow the instructions provided by your doctor. They may differ from the information contained in this leaflet.
- Do not stop taking Mycobutin unless your doctor tells you to, even if you feel better. You will usually need to take Mycobutin for a number of months.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. The bacteria may then continue to

grow and multiply so that your infection may not clear completely, or it may return.

## **When to take Mycobutin**

- Mycobutin capsules should be swallowed whole once a day. They may be taken at any time and may be taken with or without food.

## **If you forget to take Mycobutin**

Mycobutin should be taken regularly around the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## **If you take too much Mycobutin**

If you think that you have taken too much Mycobutin, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

An excessive dose may lead to severe side effects. You should inform your doctor as soon as possible.

## **5. What should I know while taking Mycobutin?**

### **Things you should do**

- Keep all appointments with your doctor and always discuss any problems you may be experiencing during your course of treatment with him/her.
- Mycobutin may affect the liver or reduce the body's ability to make red or white blood cells or platelets. Regular blood tests may be required.
- As part of your treatment, you may be given other medicines including other antibiotics. It is important to keep taking these medicines as well as Mycobutin unless you are told otherwise by your doctor or pharmacist.
- Tell your doctor immediately if you become pregnant while you are taking Mycobutin.
- If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after Mycobutin has been stopped. Diarrhoea may mean you have a serious condition affecting your bowel.

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

- Tell your doctor immediately if you have any pain, redness or blurry vision.
- Tell your doctor immediately if you have a moderate or severe skin rash or blisters often with flu-like symptoms

Remind any doctor or dentist you visit that you are taking Mycobutin.

### **Things you should not do**

- Do not stop this medicine without advice from your doctor first.
- Mycobutin has been prescribed for you by your doctor. Do not give it to anyone else, even if they seem to have the same condition as you.
- Whilst you are taking Mycobutin, do not start taking any other medicines, prescription or not, without first telling your doctor or pharmacist.

### **Things to be careful of**

- Oral contraceptives may be affected by Mycobutin. Discuss with your doctor about using a different means of birth control during treatment with Mycobutin.
- When taking Mycobutin, your urine (and possibly skin or body secretions) may become a red-orange colour.
- Contact lenses may be permanently stained. Therefore, it is better not to wear contact lenses,

particularly soft contact lenses, during a treatment course of Mycobutin.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Mycobutin affects you.**

## **Drinking alcohol**

No information available.

## **Looking after your medicine**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep your capsules in their original packaging, including outer carton, until it is time to take them.**

If you take the medicine out of the pack, it may not keep well.

Do not take this medicine after the expiry date.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Mycobutin, like all other medicines, may cause unwanted side effects. These are usually mild and disappear when you have completed the course.

Mycobutin is generally given together with other medications, so it is not always easy to identify which medicine may be causing the side effects that you may experience.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
<b>Gastrointestinal symptoms:</b> <ul style="list-style-type: none"><li>• nausea and vomiting</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<p><b>Aches and pains:</b></p> <ul style="list-style-type: none"> <li>• pain in joints and muscles</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• red-orange coloured urine or possibly discoloured skin and body secretions</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Skin symptoms:</b></p> <ul style="list-style-type: none"> <li>• jaundice (yellowing of the skin)</li> <li>• moderate or severe skin rash or blisters often with flu-like symptoms</li> </ul> <p><b>Diarrhoea:</b></p> <ul style="list-style-type: none"> <li>• diarrhoea, especially if watery and severe, which may be bloody, particularly if occurs several weeks after stopping Mycobutin.</li> </ul> <p><b>Eye disorders:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● redness, soreness of the eye, or blurry vision .</li> </ul> <p><b>Signs of an allergic reaction or difficulty breathing, such as:</b></p> <ul style="list-style-type: none"> <li>● shortness of breath, chest pain or rashes that may or may not be itchy, coughing and wheezing.</li> </ul> <p><b>Symptoms related to anaemia (a red blood cell condition) and other blood conditions</b></p> <ul style="list-style-type: none"> <li>● tiredness or pale complexion</li> <li>● unexpected bleeding or bruising</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>● fever</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

Mycobutin can also cause changes in the levels of certain chemicals in your blood and can also increase or decrease the levels of red or white cells or platelets

in your blood. This should be monitored by your doctor through regular blood tests.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Mycobutin contains

<b>Active ingredient (main ingredient)</b>	Each capsule contains 150 mg rifabutin as the active ingredient.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● microcrystalline cellulose</li><li>● sodium lauryl sulfate</li><li>● magnesium stearate</li><li>● silicon dioxide</li></ul>

- gelatin

The colorants in the capsule are

- red iron oxide
- titanium dioxide

White printing ink is used on the capsules.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Mycobutin looks like**

Mycobutin capsules are opaque and red-brown in colour with the words "Pharmacia & Upjohn" and "Mycobutin" printed on them in white ink. They are supplied in blister packs of 30 capsules

AUST R 55038.

## **Who distributes Mycobutin**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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