

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMYCOBUTIN®

Read this carefully before you start taking **MYCOBUTIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MYCOBUTIN**.

What is MYCOBUTIN used for?

- MYCOBUTIN is given to patients with advanced HIV infection.
- It is used to prevent serious disease caused by germs a group of (bacteria) called *Mycobacterium avium complex* (MAC).
- MAC may cause a lung disease like tuberculosis (TB).

Antibacterial drugs like MYCOBUTIN treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, MYCOBUTIN should be used exactly as directed. Misuse or overuse of MYCOBUTIN could lead to the growth of bacteria that will not be killed by MYCOBUTIN (resistance). This means that MYCOBUTIN may not work for you in the future. Do not share your medicine.

How does MYCOBUTIN work?

- MYCOBUTIN is an antibiotic drug that treats infections caused by germs (bacteria) called mycobacteria.
- Mycobacteria are germs (bacteria) that cannot be killed using other antibiotics.

What are the ingredients in MYCOBUTIN?

Medicinal ingredients: Rifabutin

Non-medicinal ingredients: Edible white ink, magnesium stearate, microcrystalline cellulose, red iron oxide, silica gel, sodium lauryl sulfate and titanium dioxide.

MYCOBUTIN comes in the following dosage forms:

It comes as a 150 mg capsule (pill). The capsule is dark red with the name of the drug 'PHARMACIA & UPJOHN/ MYCOBUTIN' written in white letters.

Do not use MYCOBUTIN if:

- If you are allergic (hypersensitive) to this drug.
- If you are allergic to any of the other ingredients in MYCOBUTIN (Read also "What are the ingredients in MYCOBUTIN" above.)
- If you are allergic to any drug containing rifamycin.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MYCOBUTIN. Talk about any health conditions or problems you may have, including if you:

- Have severe kidney or liver problems. (You may need a lower dose of the drug.)
- Get mild to severe diarrhea. (This could be a serious infection called *C. difficile*.)
- Get eye problems like
 - pain
 - blurred vision
 - floating dark spots in your vision
 - redness
 - sensitivity to light.

These could be signs of a problem called uveitis (inflammation in the inside of the eye.)

- Are pregnant or thinking of getting pregnant.
- If you are breast feeding your baby or thinking of breast feeding your baby.
- Have ever had an allergic reaction to any medicines.

Your health care professional will test to be sure you do not have active TB or another infection.

If you are taking MYCOBUTIN with other medicines that treat infection, you may also be asked to have regular eye exams.

Other warnings you should know about:

Taking MYCOBUTIN with anti-tuberculosis drugs can increase the risk of side effects to your skin. You may develop a serious skin condition called Severe Cutaneous Adverse Reactions (SCARs). **Speak to your doctor immediately** if you notice any skin rashes. The following skin problems may develop:

- Stevens Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). SJS and TEN are severe skin rashes. Typical symptoms include peeling skin, fever, body aches, blisters, sores, and a flat red rash
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS is serious skin reaction that may affect more than one or more organs. Typical symptoms include fever, severe rash, peeling skin, flu-like feeling, yellow skin or eyes, shortness of breath
- Acute Generalized Exanthematous Pustulosis (AGEP). AGEP is a serious skin reaction that appears suddenly. Typical symptoms include a rash of small red and white bumps and fever.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MYCOBUTIN:

- Drugs to treat diabetes
- Painkillers like acetylsalicylic acid (ASA) and others
- Narcotics, including methadone

- Blood thinners (anticoagulants) like warfarin
- Steroids (to treat inflammation or allergy) like prednisolone
- Drugs to suppress the immune system like cyclosporine (ciclosporin) and tacrolimus
- Drugs for heart conditions like quinidine or digitalis (digoxin is okay)
- Drugs to treat skin infections or pneumonia like dapsone
- Drugs to treat epilepsy or seizures like phenytoin (Dilantin)
- Drugs to treat fungal infections like fluconazole, itraconazole, posaconazole, voriconazole, ketoconazole and miconazole
- Drugs to treat viral infections like indinavir, saquinavir, ritonavir or amprenavir, atazanavir/ritonavir, darunavir/ritonavir, fosamprenavir/ritonavir, lopinavir/ritonavir, tipranavir/ritonavir, bictegrovir, doravirine, dolutegravir, Elvitegravir/ Cobicistat, Etravirine and rilpivirine
- The anti-HIV drug called delviradine
- The antibiotic drug called clarithromycin
- Birth control pills that have ethinyl estradiol and/or norethindrone. (These drugs may not be as effective if you are on MYCOBUTIN and your healthcare professional may recommend a different kind or an additional kind of birth control.)

How to take MYCOBUTIN

- It is very important to take MYCOBUTIN exactly as your healthcare professional has told you to. Never change the dose by yourself. Do not stop taking MYCOBUTIN unless your healthcare professional tells you to because your infection could return.
- Take this drug at the same time every day.
- Swallow the MYCOBUTIN capsules (pills) whole with a drink of water.

Usual dose:

- Take two MYCOBUTIN capsules (pills) by mouth once a day.
- If you have nausea, feel sick to your stomach, or throw up you can take one capsule (pill) by mouth twice a day. In this case, take with food.

Overdose:

If you think you, or a person you are caring for, have taken too much **MYCOBUTIN**, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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 missed dose.

What are the possible side effects from using MYCOBUTIN?

Some of the possible side effects are listed below. These are not all the possible side effects you may get when taking MYCOBUTIN. If you have side effects not listed here, contact your healthcare professional.

The most common side effect of MYCOBUTIN is a change in the colour of your urine from yellow to brown-orange. Colour changes like this may also affect bowel movements, spit, sweat, tears or skin. If you wear contact lenses, they may be permanently stained.

Other side effects include:

- A drop in the number of white blood cells (these fight infections).
- Skin rashes
- Stomach problems like upset stomach, burping, passing gas, nausea (feeling sick to your stomach), vomiting (throwing up) and belly pain.
- Ask your healthcare professional about how to tell if you have *Mycobacterium avium* complex (MAC) disease and/or TB.
- Let your healthcare professional know if you get any of these side effects and symptoms.

These are not all the possible side effects you may have when taking MYCOBUTIN. If you experience any side effects not listed here, tell your healthcare professional.

If you notice symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal (belly) pain, or tenderness, you may have *Clostridioides difficile* colitis (*C. difficile* – bowel inflammation). If this occurs, stop taking MYCOBUTIN and contact your healthcare professional immediately.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Diarrhea	The diarrhea is watery, bloody, or lasts for a while. You may or may not have fever or belly pain.		✓
UNCOMMON			
<ul style="list-style-type: none"> Sudden wheeziness or problems breathing 			✓
<ul style="list-style-type: none"> Pain in your chest 			✓
<ul style="list-style-type: none"> Swelling of your eyelids, face or lips 			✓
<ul style="list-style-type: none"> Rash or itching (especially over your whole body) 			✓
RARE			
<ul style="list-style-type: none"> Muscle aches 			✓
<ul style="list-style-type: none"> Uveitis: symptoms can be eye pain, blurred vision, floating dark spots, eye redness and sensitivity to light 			✓
<ul style="list-style-type: none"> Pain in a number of joints 			✓
<ul style="list-style-type: none"> Severe cutaneous adverse reactions (SCAR) (severe skin reactions that may also affect other organs): <ul style="list-style-type: none"> skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) swelling and redness of eyes or face flu-like feeling, fever, chills, body aches, swollen glands, cough shortness of breath, chest pain or discomfort 			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store your bottle of capsules at room temperature (15° to 30°C).

Keep the container tightly closed.

Keep out of reach and sight of children.

If you want more information about MYCOBUTIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling Pfizer Canada ULC at 1-800-463-6001.

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