

MYCOBUTIN[®]

CAPSULES

Rifabutin

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before taking Mycobutin. This leaflet answers some common questions about Mycobutin. It does not contain all the available information and it does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Mycobutin against the expected benefits it will have for you.

Ask your doctor if you have any concerns about taking this medicine.

Keep this leaflet with your medicine.

You may need to read it again.

What Mycobutin is used for

Mycobutin contains the active ingredient, rifabutin. It is an antibiotic, an agent used to kill certain types of germs, known as mycobacteria.

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

Before taking Mycobutin

Some information is provided below. However, always talk to your doctor if you have concerns or questions about your treatment.

When you must not take it

Do not take Mycobutin and talk to your doctor or pharmacist if:

- you are allergic to rifabutin or other rifamycin antibiotics (e.g. rifampicin)
- you are allergic to any of the other ingredients listed at the end of this leaflet
- the packaging is torn or shows signs of tampering

Do not take Mycobutin capsules after the expiry date printed on the pack has passed.

Do not give Mycobutin to children.

Do not take Mycobutin capsules if you are taking treatments that include:

- injections containing prolonged-release rilpivirine

Before you take Mycobutin

You should tell your doctor if you:

- have or have had problems with your liver or kidneys
- 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.

When taking Mycobutin, your urine (and possibly skin or body secretions) may become a red-orange colour. Contact lenses, especially soft contact lenses, may be permanently stained.

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

In particular, tell your doctor if you are taking:

- treatments for HIV, e.g. saquinavir, indinavir, ritonavir, amprenavir, fosamprenavir, lopinavir, nevirapine, bictegravir, doravirine, rilpivirine, elvitegravir/cobicistat, atazanavir/ritonavir, darunavir/ritonavir
- 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/norethindrone
- 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)

Ask your doctor or other health care professional if you are not sure about this list of medicines.

It is very important that your doctor knows all the medicines you are taking. The dose of Mycobutin or the other medicine may need to be adjusted.

How to take Mycobutin

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Mycobutin capsules should be swallowed whole once a day. They may be taken at any time and need not be taken with food.

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.

How long to take it

Continue taking Mycobutin until your doctor tells you to stop. You will usually need to take Mycobutin for a number of months.

Do not stop taking Mycobutin unless your doctor tells you to, even if you feel better.

If you do not complete the full course prescribed by your doctor, all of the germs causing your infection may not be killed. These germs may continue to grow and multiply so that your infection may not clear completely or it may return.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking Mycobutin as you would normally.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or Poisons Information Centre (telephone 0800 764 766), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Mycobutin.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

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

While taking Mycobutin

Things you must 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.

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.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Mycobutin.

Things you must not do

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.

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.

Side effects

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

Tell your doctor or pharmacist as soon as possible if you do not feel well after taking Mycobutin.

You may need medical treatment if you get certain side effects.

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.

Common side effects reported are:

- nausea or vomiting
- jaundice (yellowing of the skin)
- pain in joints and muscles
- skin rash

- fever

Less common side effects are:

- allergic reactions causing problems with breathing, or shock
- skin discolouration

Mycobutin, particularly when used with some other medicines, has been associated with mild to severe inner eye inflammation (uveitis). Tell your doctor as soon as possible if you get red sore eyes after taking Mycobutin.

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.

Tell your doctor if you have signs of anaemia (tiredness or pale complexion) or unexpected bleeding or bruising.

Tell your doctor immediately or go to the nearest hospital if you experience diarrhoea during your treatment with Mycobutin.

Tell your doctor immediately or go to the nearest hospital if you have moderate or severe skin rash or blisters often with flu-like symptoms.

Other side effects not listed above may happen in some people.

Tell your doctor as soon as possible if you experience any side effects, including any effects not listed above.

After taking Mycobutin

Tell your doctor immediately if you notice watery and severe diarrhoea which may be bloody, particularly if they occur several weeks after stopping Mycobutin.

These are rare but serious side effects. You may need urgent medical attention. Mycobutin can cause certain bacteria (that are normally harmless and present in the bowel) to multiply

Storage

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.

Keep Mycobutin in a cool dry place where the temperature stays below 25°C.

Do not store Mycobutin or any other medicines in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Mycobutin where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Mycobutin or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product Description

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

Ingredients

Each capsule contains 150 mg rifabutin as the active ingredient. Other ingredients (mainly as filling agents) are:

- microcrystalline cellulose
- sodium lauryl sulfate
- magnesium stearate
- silicon dioxide

- gelatin

The colorants in the capsule are

- red iron oxide
- titanium dioxide

White printing ink is used on the capsules.

Supplier

Pfizer New Zealand Limited

PO Box 3998

Auckland.

Toll Free Number: 0800 736 363.

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