PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MYCOBUTIN® 150 mg Capsules

Rifabutin

Sugar free

Read all of this leaflet carefully before you start taking MYCOBUTIN capsules

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MYCOBUTIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MYCOBUTIN is and what it is used for

MYCOBUTIN is an antibiotic used in combination with other medicines, for the treatment of resistant tuberculosis caused by *M. tuberculosis*.

MYCOBUTIN can be used to treat other mycobacterial infections caused by *Mycobacterium avium intracellulare complex* (MAC) or *Mycobacterium xenopi.*

2. What you need to know before you take MYCOBUTIN

Do not take MYCOBUTIN

- if you are hypersensitive (allergic) to rifabutin, other rifamycins (e.g. rifampicin) or any of the other ingredients of MYCOBUTIN (listed in section 6).
- if you have HIV/AIDS and are taking clarithromycin (used to treat bacterial infections)
- if you are currently taking ritonavir (used to treat HIV/AIDS) as this may increase the risk of side effects
- if you are currently taking ketoconazole (used to treat fungal infections)

Warnings and precautions

Take special care with MYCOBUTIN

- it is common for MYCOBUTIN to colour urine red/orange, you may also experience colouring of the skin and other body fluids
- MYCOBUTIN can permanently stain soft contact lenses
- if you have any problems with your liver or kidneys
- if you are taking clarithromycin (used to treat bacterial infections), fluconazole (used to treat fungal infections) or protease inhibitors (antiviral medicines)

If you experience pain or redness of the eye or loss of vision, contact your doctor as soon as possible as you may need to be referred to an eye specialist and treatment with MYCOBUTIN may need to be stopped.

Diarrhoea is a common problem caused by MYCOBUTIN. Sometimes after starting treatment with MYCOBUTIN, you can develop watery and bloody stools (with or without stomach cramps and fever) even more than two months after MYCOBUTIN has been stopped. If this occurs, contact your doctor as soon as possible because this may have serious consequences.

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, sores 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 severe cutaneous (skin) adverse reaction occurs during treatment with MYCOBUTIN, stop taking the medicine and and contact your doctor or seek medical attention immediately.

Your doctor will take regular blood tests to measure the level of white blood cells and red blood cells, the cells which help make the blood thicker (platelets) and functions of your liver.

Children

MYCOBUTIN is not recommended for children or adolescents.

Other medicines and MYCOBUTIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

MYCOBUTIN may affect the way in which other medicines work. You should therefore inform your doctor if you are taking any of the following medicines:

Antivirals

Amprenavir, bictegravir, delavirdine, doravirine, fosamprenavir/ritonavir, indinavir, lopinavir/ritonavir, saquinavir, rilpivirine, ritonavir, tipranavir/ritonavir, zidovudine

Antifungals

Fluconazole, itraconazole, ketoconazole, posaconazole, voriconazole

Anti-PCP (Pneumocystis jiroveci pneumonia)

Dapsone, sulfamethoxazole-trimethoprim

Anti-MAC (Mycobacterium avium intracellulare complex)

Azithromycin

Anti-tuberculosis

Ethambutol, isoniazid, pyrazinamide

Other

Tacrolimus

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

MYCOBUTIN should not be used if you are pregnant or breastfeeding.

Driving and using machines

MYCOBUTIN is not expected to have any effects on the ability to drive and use machines.

It is not always possible to predict to what extent MYCOBUTIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MYCOBUTIN affects them.

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

3. How to take MYCOBUTIN

Do not share medicines prescribed for you with any other person.

Your doctor will tell you how long your treatment with MYCOBUTIN will last. Do not stop treatment early.

The capsules should be taken by mouth, once a day. It does not matter if you take your medicine before food or after food.

MYCOBUTIN is always given in combination with other antibiotics for treating mycobacterial infections. The number of capsules depends upon the condition you are being treated for.

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

If you have the impression that the effect of MYCOBUTIN is too strong or too weak, tell your doctor

or pharmacist.

If you take more MYCOBUTIN than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MYCOBUTIN

If you forget to take your capsules, do not worry. Wait until your next dose and take the same number of capsules as usual i.e. 1 – 4. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MYCOBUTIN can have side effects.

Not all side effects reported for MYCOBUTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYCOBUTIN, please consult your health care provider for advice.

If any of the following happens, stop taking MYCOBUTIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- signs of being hypersensitive (allergic) to MYCOBUTIN such as skin rash, wheezing or faintness;
- a yellow colouring of the eyes or skin;
- shortness of breath or tight/wheezy feeling in the chest which may be associated with pain in the chest;
- a medicine 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 (SJS), toxic epidermal necrolysis (TEN). These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, sores 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, 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 generalized exanthematous pustulosis, AGEP). Stop using MYCOBUTIN if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

These are all very serious side effects. If you have them, you may have had a serious reaction to MYCOBUTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

Frequent side effects

- a reduction in the number of white cells in your blood (leukopenia), which may cause chills, fever, malaise (vague feeling of bodily discomfort), tiredness, weakness, an increased risk of infection, oral fungal infections and ulcerations
- a decrease in the amount of red blood cells or haemoglobin in your blood (anaemia), which may cause tiredness, dizziness, loss of energy, a rapid heartbeat, shortness of breath and difficulty concentrating
- nausea, vomiting
- increased substances produced by the liver known as enzymes (increased hepatic enzymes), which may cause yellowing of the skin and the whites of the eyes, enlarged or painful upper abdomen, tiredness, nausea and vomiting
- skin rash

- muscle pain
- fever/high temperature

Less frequent side effects

- a deficiency of all three cellular components of the blood (red cells, white cells, and platelets) at the same time
- a deficiency of platelets, the cells which help make the blood thicker
- an increase in the number of eosinophils, a type of white blood cell
- cloudiness of the surface of the eye
- aching joints

Other side effects

- pain or redness of the eye or loss of vision
- diarrhoea, tongue and tooth discolouration
- liver problems
- peeling or blistering of the skin, eczema
- increased levels of alkaline phosphatase in the blood

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MYCOBUTIN.

5. How to store MYCOBUTIN

- Store all medicines out of reach of children.
- Store at or below 25 °C.

- Protect from light and moisture.
- Do not store on a windowsill or in a steamy bathroom.
- The label carries an expiry date. Do not use the medicine after this date. If necessary, get a new prescription from your doctor.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYCOBUTIN contains

- The active substance is rifabutin.
- Each capsule contains 150 mg rifabutin.
- The other ingredients in MYCOBUTIN are gelatine, magnesium stearate, microcrystalline cellulose, red iron oxide, silica gel, sodium lauryl sulphate, and titanium dioxide.

What MYCOBUTIN looks like and contents of the pack

Red-brown, hard gelatine capsule, containing a violet powder.

MYCOBUTIN is presented in foil-covered blister packs of 30 or 100 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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