

Mycofaz

Clofazimine Film Coated Tablets (50mg and 100mg)

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1. What Mycofaz Used For:

Clofazimine is used together with other medicines to treat some forms of leprosy.

Combination with other medicines e.g., with rifampicin or dapsone is necessary to prevent the development of drug resistance.

2. How Mycofaz Works:

Mycofaz contains active ingredient clofazimine which is an anti-mycobacterial medicine that stops the growth of mycobacteria in the body and/or eventually kills them.

3. Before You Use Mycofaz

When you must not use it

Do not use Mycofaz if:

- you are allergic (hypersensitive) to Clofazimine or any of the other ingredients.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breastfeeding before using any medicine.

Do not take Mycofaz if you are pregnant, trying to get pregnant or think you may be pregnant, unless instructed by your doctor.

Skin discoloration of your baby may occur if Mycofaz were used during pregnancy.

Clofazimine is secreted into the breastmilk and skin discoloration may occur in the infant. Therefore, breastfeeding is not recommended during treatment with Mycofaz.

Before you start to use it

Talk to your doctor or pharmacist before using Clofazimine you have or history of:

- stomach or bowel problems
- depression

Taking other medicines:

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

4. How To Use Mycofaz

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

For leprosy

Adult:

Take clofazimine 300mg under doctor's supervision once a month and clofazimine 50mg once a day, together with other medicines.

Children (10-14 years):

Take clofazimine 200mg under doctor's supervision once a month and clofazimine 50mg once a day, together with other medicines.

Type II leprosy

Adult and children: Clofazimine dose may increase up to 200-300mg daily under doctor's supervision, with rifampicin and dapsone dose to continue as before.

When to use it:

Mycofaz should be taken with meals or milk to ensure maximum

absorption. Use as directed by your doctor or pharmacist.

How long to use it:

Take Clofazimine for as long as your doctor recommends.

For lepromatous leprosy
To be taken for at least 2 years, until all infection is cleared.

Erythema nodosum leprosum
Do not take high daily dose for more than 3 months.

If You Forget To Use Mycofaz:

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use Mycofaz too much (Overdose):

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

5. While You Are Using Mycofaz - Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Mycofaz.

Tell your doctor immediately if you become pregnant while taking this medication.

Take Mycofaz only with a doctor's prescription.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

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Do not take any new medicines without consulting your doctor.

Do not give Mycofaz to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of:

If you have abdominal pain, nausea, vomiting, or diarrhea, tell your doctor.

Apply oil if you are having skin dryness.

If possible, avoid the sun and use sunscreens to protect your skin from sunlight.

Be careful driving or operating machinery until you know how Mycofaz affects you.

6. Side Effects

Like all medicines, Clofazimine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Skin:

Mycofaz may discolor your skin from pink to brownish black within a few weeks after you start taking it. Discoloration will go away when you stop taking.

If skin discoloration causes you to feel depressed, see your doctor as soon as possible.

Other skin reactions include rough, dry and scaly skin, rash and itchiness.

Gastrointestinal:

Abdominal and epigastric pain, diarrhea, nausea, vomiting, gastrointestinal intolerance (very common).

Ocular:

Irritation of the eyes (itching, burning, dryness). It also may cause eye discoloration, but once you

stop taking, eye color should return to normal.

Other:

Discoloration of the body urine, feces, sputum, sweat), elevated blood sugar; signs of inflammation (elevated erythrocyte sedimentation rate (ESR)).

Other serious side effects include inflammation of the liver, blood clot that gets stuck and causes an obstruction, and low red blood cells (anemia). If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage And Disposal Of Mycofaz

Storage

Do not store above 30°C, protect from light. Excursions above 30°C are not allowed.

Keep out of the reach and sight of children.

Do not use clofazimine after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

Disposal

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

8. PRODUCT DESCRIPTION

What it looks like and contents of the pack

For 50 mg: Light brown colored, circular shaped, biconvex, film coated tablets plain on both sides.

For 100 mg: Light brown colored, oval shaped, biconvex, film coated tablets, with scoreline on one side and plain surface on other side.

Pack Sizes:

For 50 mg:

- Alu/PVC/PVdC blister pack of 28 Tablets, such 10 blisters are packed in a carton along with pack insert.

- Alu/PVC/PVdC blister pack of 10 Tablets, such 10 blisters are packed in a carton along with pack insert.

- Alu/Alu Strip pack of 10 Tablets, such 10 strips are packed in a carton along with pack insert.

For 100 mg:

- Alu/Alu Strip pack of 10 Tablets, such 10 strips are packed in a carton along with pack insert.

What Mycofaz Contains

The active substance is clofazimine.

The other ingredients are:

Castor oil polyoxyl hydrogenated, povidone, polysorbate 80, betadex, microcrystalline cellulose, colloidal silicon dioxide, crospovidone, sodium stearyl fumarate, Instacoat Universal Brown, Isopropyl alcohol and Methylene Chloride and Purified water.

- MAL Number:

50mg: MALXXXXXXXXXXXX

100mg: MALXXXXXXXXXXXX

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9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer:

Oxalis Labs

Village Theda, P.O. Lodhimajra,
Tehsil Baddi, District Solan,
Himachal Pradesh, India

Product Registration Holder:

Macleods Pharmaceutical Sdn. Bhd.,

A2-27-1 Soho Suites KLCC, Jalan
Perak, 50450 Kuala Lumpur,
Malaysia.

10. Date of revision:

16/04/2025

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