

## **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.\**

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

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\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

[TB361 trade name]<sup>†</sup>  
Clofazimine

*If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.*

### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What [TB361 trade name] is and what it is used for
2. What you need to know before you take [TB361 trade name]
3. How to take [TB361 trade name]
4. Possible side effects
5. How to store [TB361 trade name]
6. Contents of the pack and other information

#### **1. What [TB361 trade name] is and what it is used for**

[TB361 trade name] is a medicine used to treat tuberculosis (TB), an infection caused by a bacteria called *Mycobacterium tuberculosis*. It is always given together with other medicines to treat tuberculosis. Your health care provider has chosen the combination that is right for your condition.

[TB361 trade name] contains the active ingredient clofazimine.

#### **2. What you need to know before you take [TB361 trade name]**

##### **Do not take [TB361 trade name] if:**

- you are allergic (hypersensitive) to clofazimine or any of the other ingredients of [TB361 trade name] (see section 6, 'What [TB361 trade name] contains').

##### **Warnings and precautions:**

Always take [TB361 trade name] with other tuberculosis medicines that your health care provider has asked you to take.

Speak with your health care provider before taking [TB361 trade name] if:

- you have or have had heart rhythm problems, or if someone in your family has heart rhythm problems
- you have heart failure
- your thyroid is not or has not been working well enough
- your blood tests show reduced levels of calcium, magnesium or potassium in your blood

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

If any of the following applies to you, tell your health care provider immediately:

- If you get belly or stomach pain, severe nausea (feeling sick), vomiting, cramps or burning during treatment with [TB361 trade name]. Your health care provider may need to check the cause of these effects and may decide to change your medicine.
- Abnormalities in the electrocardiogram (ECG, electrical recording of the heart), called QT interval prolongation, may occur during treatment. Your health care provider will check your ECG to decide if you can take [TB361 trade name]. The health care provider may also check your ECG during your treatment. Your health care provider may adjust your treatment if the ECG is abnormal. Also, you may have blood tests to check your levels of potassium, calcium and magnesium.  
Tell your health care provider if you feel dizzy (or you faint) or you feel your heart pounding (palpitations).

[TB361 trade name] discolours the skin, eyes and body fluids. Speak with your health care provider if changes in your skin colour are causing you concern.

If possible, avoid the sun and use strong sunscreens to protect your skin from sunlight. This is because sunlight can damage your skin while you are taking [TB361 trade name].

### **Taking other medicines with [TB361 trade name]**

Tell your health care provider if you are taking or have taken any medicines, including medicines obtained without a prescription. In particular, talk to your health care provider if you are taking any of the following medicines:

- bedaquiline or delamanid (other treatments for tuberculosis [TB])
- fluoroquinolone antibiotics such as moxifloxacin, levofloxacin, or gatifloxacin, used for treating TB or other bacterial infections
- macrolide antibiotics such as azithromycin and erythromycin for the treatment of bacterial infections
- efavirenz or some other antiretrovirals for the treatment of HIV infection
- azole antifungals such as fluconazole and voriconazole used to treat infections caused by fungi or moulds
- metoclopramide used to treat nausea, vomiting, or heartburn
- certain diuretics (medicine that makes you pass water): furosemide, hydrochlorothiazide
- citalopram or escitalopram used to treat depression
- methadone used for the treatment of addiction
- medicines to treat heart rhythm problems

It may still be alright for you to take [TB361 trade name] and your health care provider will decide what is suitable for you.

### **Pregnancy and breast-feeding**

If you become pregnant, think you may be pregnant, or are trying to become pregnant, talk to your health care provider about your treatment for tuberculosis. Clofazimine passes into breast milk. Talk to your health care provider if you are thinking of breast-feeding your baby.

### **Driving and using machines**

[TB361 trade name] may cause dizziness, impaired concentration, and drowsiness. If it affects you in this way do not drive, operate machinery or do anything that requires you to be alert. Remember that if you are unwell, your ability to drive or operate machinery may be affected.

### **Excipients with known effects**

[TB361 trade name] contains castor oil polyoxyl hydrogenated and betadex (cyclodextrins). These ingredients may cause digestive problems, including stomach upset and diarrhoea.

## **3. How to take [TB361 trade name]**

You must always take [TB361 trade name] together with other medicines for treating tuberculosis.

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Take [TB361 trade name] with food. This may make some side effects (stomach upset) less troublesome.

Swallow the tablets with water. If you cannot swallow tablets, or for young children, the tablets can be mixed with drinking water (see *How to prepare the mixture*, below).

## Dose

### *Adults and teenagers weighing at least 46 kg*

The usual dose is 2 tablets of [TB361 trade name] once daily.

### *Children and teenagers weighing less than 46 kg*

The dose of [TB361 trade name] for a child is calculated according to the child's weight. The recommended dose in children is 2–5 mg/kg.

Depending on the child's weight, the child will need to take [TB361 trade name] either every day or only on certain days of the week. Your health care provider will explain how much and how often to give [TB361 trade name]. The usual doses are:

Child's weight	Dose
3 to less than 5 kg	1 tablet on <b>2 days each week</b> (for example on Mondays and Fridays)
5 to less than 10 kg	1 tablet on <b>3 days each week</b> (for example on Mondays, Wednesdays and Fridays)
10 to less than 24 kg	1 tablet once daily
24 to less than 46 kg	2 tablets once daily

Your health care provider will tell you how long you or your child will be given [TB361 trade name].

If the tablets need to be mixed with drinking water, follow the steps below.

### *How to prepare the mixture*

1. Put 1 tablet of [TB361 trade name] in a cup or a glass and add 5 mL (about one teaspoonful) of drinking water. Use 10 mL (2 teaspoonfuls) drinking water for 2 tablets to give to those weighing at least 24 kg.
2. Let it sit for about 5 minutes, until the tablet breaks down completely.
3. Stir the mixture well and give it to the child straight away.
4. To make sure that the child gets the full dose, rinse the cup or glass with a small amount of water (one or two teaspoonfuls) and get the child to drink it all, or use a spoon to give the remaining mixture.

### **If you take more [TB361 trade name] than you should**

If you accidentally take more [TB361 trade name] than you should, contact your health care provider or the nearest emergency department for advice. Take the medicine pack and this leaflet with you so that you can easily describe what you have taken.

### **Do not forget to take [TB361 trade name]**

It is important not to miss a dose. Your treatment may not work if you do not take your TB medicines correctly.

**If you vomit (throw up) within 1 hour of taking [TB361 trade name]**, take another tablet. Do not wait until your next dose is due. You do not need to take another tablet if you vomit more than an hour after taking [TB361 trade name].

If you have any questions on the use of this medicine, ask your health care provider.

### **If your health care provider temporarily stops your treatment**

If you get certain side effects, your health care provider may stop your treatment for a short time. When restarting treatment, your health care provider will tell you how to make up for the missed doses to complete the full course, or what dose to take. Rarely, your health care provider may decide that a different treatment is more suitable for you.

#### **4. Possible side effects**

Like all medicines, [TB361 trade name] can cause side effects, but not everybody gets them. Tell your health care provider about any change in your health.

#### **Possibly serious side effects**

**Tell your health care provider immediately** if you get any of the following symptoms:

- bloody or black stools or diarrhea
- lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash  
*and you have any of the following*
  - belly pain, usually on the right side and near the chest
  - unexplained itching
  - yellowing of the white parts of your eyes, your nails or your skin
  - passing dark urine
  - passing stools that are very pale

These are signs of a problem with your liver, which can become serious.

- severe nausea (feeling sick), vomiting, belly or stomach pain, cramps or burning
- feel dizzy (or you faint) or you feel your heart pounding (palpitations). These could be signs of problems with your heart related to abnormalities in the electrocardiogram (ECG, electrical recording of the heart), a condition called QT interval prolongation.
- depression or thoughts of hurting yourself

The following side effects can also occur with clofazimine:

#### **Most frequent side effects**

- orange, pink to brown-black discoloration of the skin, eyes and body fluids (urine, faeces, sputum, sweat) within a few weeks of treatment
- dry skin, thick scaly skin
- rash
- itching
- belly or stomach pain
- diarrhoea
- nausea (feeling sick)
- vomiting (being sick)
- stomach pain
- problems with your vision
- irritation of the eyes (itching, burning, dryness)

*Blood tests may also show*

- signs of inflammation (raised erythrocyte sedimentation rate, ESR)
- increased blood sugar

#### **Less common side effects**

- sunburn-like reactions (following exposure to light)
- inflamed, flaky skin
- acne-like rash
- skin cracks or tears in the corners of the mouth caused by a yeast infection
- bowel obstruction

- loss of appetite
- constipation
- weight loss
- inflammation and injury in the small intestine caused by in a certain type of white blood cells (eosinophils)
- enlarged liver
- damage to the retina
- feeling dizzy, problems with balance
- feeling sleepy
- tiredness
- nerve pain
- taste disturbances
- splenic infarction (painful condition in which blood flow supply to the spleen is blocked); you may have sudden and severe pain in your upper left belly, feel sick, and have fever
- blood clots in blood vessels
- inflammation in the bladder which can cause pain and discomfort when passing urine
- bone pain
- fever
- swelling, usually of ankles because of a build-up of fluid
- enlarged lymph nodes
- vascular pain – discomfort because blood does not flow properly

*Blood tests may also show*

- liver problems
- increases in a certain type of white blood cells (eosinophils) in the blood
- decreases in potassium in the blood
- low red blood cell counts which can cause tiredness and pale skin

If any side effects get serious or if you notice any side effects not listed in this leaflet, please tell your health care provider.

### **Reporting of side effects**

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

### **5. How to store [TB361 trade name]**

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Protect from light. Avoid excursions above 30°C.

Do not use this medicine after the expiry date stated on the label after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

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.

### **6. Contents of the pack and other information**

#### **What [TB361 trade name] contains**

- The active ingredient is clofazimine.
- The other ingredients of [TB361 trade name] are castor oil polyoxyl hydrogenated, povidone, polysorbate 80, betadex (cyclodextrin), microcrystalline cellulose, colloidal silicon dioxide,

crospovidone, sodium stearyl fumarate, hypromellose, triacetin, titanium dioxide, iron oxide red and iron oxide yellow.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

**What [TB361 trade name] looks like and contents of the pack**

Light brown, round, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets are plain on both sides.

*HDPE container:*

Round white plastic (HDPE) containing 100 tablets. The bottle has a white plastic (HDPE) child-resistant closure with pulp and a white printed liner.

*Blister pack:*

Clear colourless plastic (PVC/PVDC) on aluminium foil blister cards, each containing 10 or 28 tablets. Available in cartons of 10×10 and 10×28 tablets.

*Strip pack:*

Aluminium foil strip packs, each containing 10 tablets. Available in cartons of 10×10 tablets.

**Supplier and Manufacturer**

***Supplier***

Macleods Pharmaceuticals Limited  
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For any information about this medicine, contact the local representative of the supplier.

**This leaflet was last revised in March 2026**

*Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>*