

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.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB364 trade name][†]
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 [TB364 trade name] is and what it is used for
2. What you need to know before you take [TB364 trade name]
3. How to take [TB364 trade name]
4. Possible side effects
5. How to store [TB364 trade name]
6. Contents of the pack and other information

1. What [TB364 trade name] is and what it is used for

[TB364 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.

[TB364 trade name] contains the active ingredient clofazimine.

2. What you need to know before you take [TB364 trade name]

Do not take [TB364 trade name] if:

- you are allergic (hypersensitive) to clofazimine or any of the other ingredients of [TB364 trade name] (see section 6, 'What [TB364 trade name] contains').

Warnings and precautions:

Always take [TB364 trade name] with other tuberculosis medicines that your health care provider has asked you to take.

Speak with your health care provider before taking [TB364 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

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- your blood tests show reduced levels of calcium, magnesium or potassium in your blood

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 [TB364 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 [TB364 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).

[TB364 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 [TB364 trade name].

Taking other medicines with [TB364 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 [TB364 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

[TB364 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.

[TB364 trade name] contains soybean oil

If you are allergic to peanut or soya, do not use this medicinal product.

[TB364 trade name] contains glycerin

Glycerin may cause headache, stomach upset and diarrhea.

3. How to take [TB364 trade name]

You must always take [TB364 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 [TB364 trade name] with food. This may make some side effects (stomach upset) less troublesome.

Swallow the capsules whole with water.

Dose

Adults and teenagers weighing at least 46 kg

The usual dose is 1 capsule of [TB364 trade name] once daily.

Children and teenagers weighing less than 46 kg

The dose of [TB364 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 [TB364 trade name] either every day or on certain days of the week. Your health care provider will explain how much and how often to give [TB364 trade name]. The usual doses are:

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

Your health care provider will tell you how long you or your child will be given [TB364 trade name].

If you take more [TB364 trade name] than you should

If you accidentally take more [TB364 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 [TB364 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 [TB364 trade name], take another capsule. Do not wait until your next dose is due. You do not need to take another capsule if you vomit more than an hour after taking [TB364 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, [TB364 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 [TB364 trade name]

Do not store above 30°C.

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

Do not use this medicine after the expiry date stated on the bottle 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 [TB364 trade name] contains

- The active ingredient is clofazimine. Each soft capsule contains 100 mg clofazimine.
- The other ingredients of [TB364 trade name] are:

Capsule fill: Soybean oil, canola oil, hydrogenated vegetable oil, white beeswax, lecithin, butylated hydroxytoluene.

Capsule shell: Gelatin, glycerine, ethyl vanillin, black iron oxide, red iron oxide, methylparaben, propylparaben.

What [TB364 trade name] looks like and contents of the pack

[TB364 trade name] is a brown opaque, oval soft capsule, the capsules are plain and have no markings. They are filled with brick red to brown suspension.

HDPE bottle

[TB364 trade name] is available in a white HDPE bottle containing 100 capsules. It also contains 1g silica gel stick and closed with white low density polyethylene cap.

Supplier and Manufacturer

Supplier

Dong-A ST Co. Ltd
64, Cheonho-daero
Dongdaemun-gu
Seoul 130 708
Republic of Korea
Tel: +82-80-920-8524
Fax: +82-2-924-2662
E-mail: doha@donga.co.kr

Manufacturer

Suheung Co. Ltd
Osong Plant (Head Office)
61, Osongsaengmyeong-ro
Osong-eup, Heungdeok-gu, Cheongju-si
Chungcheongbuk-do
Republic of Korea

Dong-A ST Co., Ltd
Cheonan Plant (2F Section B, 3F, 4F Section B)
200-23, Baekseokgongdan 1-ro
Seobuk-gu, Cheonan-si
Chungcheongnam-do
Republic of Korea
E-mail: chemy5@suheung.com

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>