

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/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB364 trade name][†]
Clofazimine

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 has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem 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] contains the active ingredient clofazimine.

Clofazimine is an antibiotic which is used together with other medicines to treat tuberculosis (TB) caused by bacteria called *Mycobacterium tuberculosis*.

Clofazimine is only indicated as a second-line antimycobacterial drug when first-line drugs cannot be used because of resistance or intolerance.

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].

Take special care with [TB364 trade name]:

- if you experience 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 examine the cause of these effects and may decide to change your medication.
- [TB364 trade name] causes discolouration of the skin, eyes and body fluids. If possible, avoid the sun and use strong sunscreens to protect your skin from sunlight.

If any of the above applies to you, tell your health care provider immediately.

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:

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

- bedaquiline or delamanid (other treatments for tuberculosis [TB])
- fluoroquinolone antibiotics such as moxifloxacin or gatifloxacin (used for the treatment of TB or other bacterial infections)
- efavirenz or other antiretrovirals for the treatment of HIV infection
- azole antifungals (used to treat infections caused by fungi or moulds)

It may still be alright for you to be given [TB364 trade name] and your health care provider will be able to decide what is suitable for you.

Pregnancy and breast-feeding

Tell your health care provider if you are pregnant or trying to become pregnant. Your health care provider can explain the risks and benefits of your therapy to you and your child.

If you are interested in breast-feeding your baby, you should discuss the risks and benefits with your healthcare provider.

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]

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

[TB364 trade name] will always be taken together with other antituberculosis medication; please make sure to follow the instructions within the supplied patient information leaflet.

[TB364 trade name] should be taken with food. This may make some side effects (stomach upset) less troublesome. The tablet should be taken with water and swallowed whole.

Dose

Adults and adolescents 15 years or older

The usual dose is one tablet taken each day by mouth.

Children and adolescents younger than 15 years

The dose of clofazimine for a child is calculated according to the child's body weight. The recommended dose in children is 2–5 mg/kg. [TB364 trade name] may need to be taken every day, every other day, or on certain week days. Your health care provider will tell you how often your child needs to take [TB364 trade name].

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 too many [TB364 trade name], you may be at increased risk of experiencing possible side effects with this medicine (see section 4, *Possible side effects*). Contact your health care provider or the nearest emergency department for advice. Take the tablet container with you so that you can easily describe what you have taken.

If you forget to take [TB364 trade name]:

It is important not to miss a dose.

If you throw up within 1 hour of taking [TB364 trade name], you should take another tablet. Do not wait until your next dose is due. You do not need to take another tablet if you threw up more than an hour after taking [TB364 trade name].

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

4. Possible side effects

Like all medicines, clofazimine 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
- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by inflammation of the liver
- severe nausea (feeling sick), vomiting, belly or stomach pain, cramps or burning
- depression or thoughts of hurting yourself

The following side effects can also occur with clofazimine:

Most frequent side effects

- pink to brownish-black discolouration of the skin, eyes and body fluids (urine, feces, sputum, sweat) within a few weeks of treatment
- dry skin, thick scaly skin
- rash
- itching
- belly or stomach pain
- diarrhea
- nausea (feeling sick)
- vomiting
- gastrointestinal intolerance
- diminished vision
- irritation of the eyes (itching, burning, dryness)

Tests may also show

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

Less common side effects

- sunburn-like reactions (following exposure to light)
- inflamed, flaky skin
- acne-like eruptions
- fissures in one or both corners of the mouth caused by an infection with a yeast (*C. albicans*)
- bowel obstruction
- loss of appetite
- constipation
- weight loss
- inflammation of, and injury to 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
- fatigue
- nerve pain
- taste disturbances
- splenic infarction (painful condition in which blood flow supply to the spleen is blocked)

- problems due to the formation of blood clots in the blood vessels
- inflammation in the bladder which can cause pain and discomfort when passing urine
- bone pain
- fever
- swelling
- enlarged lymph nodes
- vascular pain

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 any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

5. How to store [TB364 trade name]

Do not store above 30°C.

Keep out of the reach and sight of children.

Do not use [TB364 trade name] after the expiry date which is stated on the bottle after “EXP”. The expiry date refers to the last day of that month.

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 substance is clofazimine. Each soft capsule contains 100 mg clofazimine.

The other ingredients 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 [TB362 trade name] looks like and contents of the pack

Brown opaque, oval soft capsule filled with brick red to brown suspension.

HDPE bottle:

White HDPE bottle with 1g silica gel stick and closed with white low density polyethylene cap. Pack size: 100 capsules.

Supplier and Manufacturer

Supplier

Dong-A ST Co. Ltd.
64, Cheonho-daero
Dongdaemun-gu
Seoul 130 708
Republic of Korea
tel: +82-80-920-8111
fax: +82-2-924-2662
e-mail: dasomkim@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

For any information about this medicine, contact the supplier:

This leaflet was last revised in February 2021

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>