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/documents/75%20SRA%20clarification_February2017_0.pdf

Information for the patient

[TB361 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 [TB361 trade name] is and what it is used for

[TB361 trade name] contains the active ingredient clofazimine.

Clofazimine is an antibiotic which is used together with other medicines to treat tuberculosis (TB) caused by a 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 [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].

Take special care with [TB361 trade name]:

- if you experience 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 examine the cause of these effects and may decide to change your medication.
- [TB361 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.

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

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 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 [TB361 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

[TB361 trade name] may make you feel dizzy, tired or experience problems with your vision. 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.

[TB361 trade name] contains castor oil polyoxyl hydrogenated

[TB361 trade name] contains castor oil polyoxyl hydrogenated, which may cause stomach upset and diarrhoea.

[TB361 trade name] contains betadex (cyclodextrin)

Cyclodextrins may cause digestive problems such as diarrhoea.

3. How to take [TB361 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.

[TB361 trade name] will always be taken together with other antituberculosis medication; please make sure to follow the instructions within the supplied patient information leaflet.

[TB361 trade name] should be taken with food. This may make some side effects (stomach upset) less troublesome. The tablets should be taken with water and swallowed whole.

Dose

Adults and adolescents 15 years or older
The usual dose is two tablets 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. [TB361 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 [TB361 trade name].

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

If you take more [TB361 trade name] than you should:
If you accidentally take too many [TB361 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 [TB361 trade name]:
It is important not to miss a dose.

If you throw up within 1 hour of taking [TB361 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 [TB361 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 [TB361 trade name]

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

Keep out of the reach and sight of children.

Do not use [TB361 trade name] after the expiry date which is stated on the container 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 [TB361 trade name] contains

The active substance is clofazimine. Each film-coated tablet contains 50 mg clofazimine.

The other ingredients are:

Core tablet: castor oil polyoxyl hydrogenated, povidone, polysorbate 80, betadex (cyclodextrin), microcrystalline cellulose, colloidal silicon dioxide, crospovidone, sodium stearyl fumarate.

Film coat: hypromellose, triacetin, titanium dioxide, iron oxide red, iron oxide yellow.

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

Light brown-coloured, circular-shaped, biconvex, film-coated tablet and plain on both sides.

HDPE container:

Round white HDPE container closed with white polypropylene child resistant closure with pulp and white printed liner. Pack size: 100 tablets.

Blister pack:

Clear PVC/PVDC-aluminium blister. Each blister contains 10 or 28 tablets. 10 blisters are packed in a carton. Pack sizes: 10 x 10 tablets, and 10 x 28 tablets.

Strip pack:

Plain aluminium foil laminated with polyethene film strip. Each strip contains 10 tablets. 10 such strips are packed in a carton. Pack size: 10 x 10 tablets.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the supplier.

This leaflet was last revised in November 2020

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