

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.

Information for the patient

[TB397 trade name][†]

Pretomanid

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 [TB397 trade name] is and what it is used for
2. What you need to know before you take [TB397 trade name]
3. How to take [TB397 trade name]
4. Possible side effects
5. How to store [TB397 trade name]
6. Contents of the pack and other information

1. What [TB397 trade name] is and what it is used for

[TB397 trade name] is a medicine used to treat tuberculosis (TB), an infection caused by 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.

[TB397 trade name] contains the active substance pretomanid.

Pretomanid works by stopping the tuberculosis bacteria from building cell walls and also by triggering production of substances that poison the bacteria.

2. What you need to know before you take [TB397 trade name]

Do not take [TB397 trade name]:

- if you are allergic to pretomanid, other antibiotics of a group called nitroimidazoles, or to any of the other ingredients of [TB397 trade name] (see section 6, 'What [TB397 trade name] contains').

Speak to your health care provider if you think you should not take this medicine.

Warnings and precautions

Speak with your health care provider before taking [TB397 trade name] if:

- you have problems with your liver
- you have problems with your kidneys
- you regularly drink alcohol

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

- 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

Liver damage

Some people get problems with their liver with [TB397 trade name] treatment. Your health care provider will do blood tests to check how well your liver is working before you take [TB397 trade name]. The health care provider will continue the tests during your treatment.

Speak with your health care provider straightaway if you:

- 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 your skin or 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.

Heart problems

A condition with 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 before deciding if you can take [TB397 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. In addition, 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).

Other problems you should tell your health care provider about

Your health care provider may suggest changing your treatment if any of the following occur:

- Extreme tiredness, bruising, bleeding or infection — possible signs of blood problems
- Visual problems, numbness, tingling or burning in your hands and feet — possible signs of nerve problems
- Continuous nausea (feeling sick) or vomiting — possible sign of a condition called lactic acidosis

Children and adolescents

[TB397 trade name] is not recommended for children and adolescents younger than 14 years or weighing less than 30 kg because it has not been studied in this age group.

Other medicines and [TB397 trade name]

Tell your health care provider if you are taking or have recently taken any medicines, including medicines obtained without prescription and herbal medicines. Some medicines can change how well [TB397 trade name] works or may increase the side effects of [TB397 trade name] or of other medicines.

Tell your health care provider straightaway if you take any of these medicines:

- rifabutin, rifampicin, rifamycin, rifapentine: other medicines to treat tuberculosis or certain other infections
- efavirenz, etravirine, nevirapine: medicines used for HIV infection
- carbamazepine, phenytoin: medicines to treat epilepsy and certain pain conditions
- St John's wort: a herbal medicine to treat depression and anxiety

These may reduce how well [TB397 trade name] works. Therefore, do not take [TB397 trade name] and any of these medicines at the same time.

You should also not take medicines that may cause liver problems (other than bedaquiline and linezolid). Your health care provider will tell you which medicines this applies to.

Tell your health care provider if you are using:

- methotrexate: a medicine to treat severe joint inflammation, cancer and the skin disease psoriasis
- benzylpenicillin, ciprofloxacin: medicines to treat bacterial infections
- indometacin: a medicine to treat pain and inflammation

[TB397 trade name] with food and drink

Taking [TB397 trade name] with food increases the amount of medicine that gets into your body.

[TB397 trade name] with alcohol

Avoid drinking alcohol regularly while being treated with [TB397 trade name] since this can increase the risk of serious liver problems.

Pregnancy and breast-feeding

You should not become pregnant while on treatment with [TB397 trade name]. If you become pregnant, think you may be pregnant, or are planning to become pregnant, talk to your health care provider about your treatment for tuberculosis.

Pretomanid passes into your milk. Talk to your health provider if you are thinking of breast-feeding your baby.

Driving and using machines

You may feel dizzy after taking [TB397 trade name] or you may get problems with your vision. Do not drive or operate machinery if this happens.

Other ingredients of [TB397 trade name]

This medicine contains lactose. Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

3. How to take [TB397 trade name]

Always take [TB397 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

[TB397 trade name] is used in combination with other medicines for treating tuberculosis. You must also read the package leaflets for these medicines. If you have any questions, ask your health care provider.

Your TB treatment may need to continue for many months. It is important to take the full course of treatment, even if you feel better.

Adults and adolescents 14 years and older (weighing at least 30 kg)

The recommended dose of [TB397 trade name] is 1 tablet once daily. Take the medicine for as long as your health care provider has told you.

Swallow each tablet whole with some water. Take [TB397 trade name] with food.

If you take more [TB397 trade name] than you should

Contact your health care provider or the nearest hospital emergency department for advice. Take a pack of your medicines with you to show the hospital what you have taken.

If you forget to take [TB397 trade name]

Do not take a double dose to make up for a forgotten dose. Talk to your health care provider if you have missed a dose and you are not sure what to do.

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.

If you stop taking [TB397 trade name]

Keep taking the medicine regularly for as long as your health care provider has told you. If you stop the medicine too soon, your infection may not be cured. In addition, the bacteria may become resistant to these medicines if you stop too soon.

You should not stop treatment unless your health care provider tells you to.

If you have any questions about this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, [TB397 trade name] can cause side effects, although not everybody gets them.

The side effects listed below can occur when [TB397 trade name] is used together with linezolid and bedaquiline.

Tell your health care provider straightaway if you get any of the following:

Very common (can occur in more than 1 person in 10 who take the medicine)

- blood tests showing a reduced number of red blood cells
Possible signs are pale skin, feeling tired, weak, being breathless or dizzy.
- blood tests showing increased levels of liver enzymes called
 - GGT (indicating how well your liver is working)
 - transaminase such as ALT, AST

This may be a sign of liver injury. Speak with your health care provider straightaway if you:

- 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.

Common (can occur in up to 1 person in 10 who take the medicine)

- blood tests showing reduced number of white blood cells (cells that help the body to fight infections) or blood platelets (cells that help the blood to clot)
Possible signs are abnormal bruising or bleeding or infections.
- lactic acidosis (too much lactic acid in the blood)
Tell your health care provider if you have recurrent nausea and vomiting, abdominal (belly) pain, or you are breathing rapidly.

Other side effects may occur:

Very common (can occur in more than 1 person in 10 who take the medicine)

- feeling sick (nausea), being sick (vomiting), indigestion
- acne

- decreased appetite
- nerve problems in the hands or feet, such as pain, burning, abnormal sensation or numbness

Common (can occur in up to more than 1 person in 10 who take the medicine)

- sleeping difficulties
- weakness, fatigue
- taste disturbance
- dizziness, headache
- muscle and bone pain, such as joint pain, back pain, muscle pain, muscle spasm, stiffness
- diarrhoea, constipation
- inflammation of stomach lining (gastritis), pancreas inflammation, abdominal (belly) pain
- acid reflux (stomach content flowing back up in the food pipe)
- dry skin, itching, rash, hair loss,
- irritation or pain of the eye, dry eye, vision problems
- optic nerve damage
- blood tests showing increased levels of bilirubin, alkaline phosphatase, creatine phosphokinase, urea, lipase, amylase, creatinine
- blood tests showing decreased levels of sugar or magnesium

Uncommon (can occur in up to 1 person in 100 who take the medicine)

- fungal infection (including candida and yeast) in the mouth or the corners of the mouth or throat, which appears as white patches
- too much fluid loss, reduced body fluid
- anxiety, depression
- enlarged liver, excessive bilirubin which can cause yellowing of the skin, nails and whites of the eyes (jaundice)
- eye lens disorder
- worsening ability to focus clearly on close objects
- eye itching, eye swelling
- optic disc swelling (leading to loss of vision)
- deafness
- feeling of rapid, irregular or forceful heartbeat
- rapid heartbeat
- low blood pressure
- cough, nosebleed
- feeling bloated
- burning or tingling sensation in or around the mouth
- eczema, excessive skin pigmentation
- inability to have or maintain an erection
- bleeding from the womb at irregular intervals, particularly between menstrual periods
- feeling unwell
- vomiting blood
- blood and urine tests indicating kidney injury
- blood tests showing decreased levels of calcium

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your health care provider as soon as possible.

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 [TB397 trade name]

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

Do not store 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 [TB397 trade name] contains

- The active ingredient is pretomanid 200 mg.
- The other ingredients of [TB397 trade name] are Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, sodium lauryl sulfate, povidone, colloidal silicon dioxide and magnesium stearate.

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

What [TB397 trade name] looks like and contents of the pack

White to off-white, oval, uncoated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have 'K31' debossed (stamped into) one side and are plain on the other side.

[TB397 trade name] is packaged in aluminium foil on aluminium foil blister cards, each containing 10 tablets. Available in cartons of 10 x 10 or 12 x 10 tablets

Supplier and Manufacturer

Supplier

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

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