

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

## Information for the patient

[TB397 trade name]<sup>†</sup>

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.

#### 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').

##### Warnings and precautions:

Always take [TB397 trade name] with other tuberculosis medicines that your health care provider has asked you to take.

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
- 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

---

<sup>†</sup> 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

#### *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 deciding if you can take [TB397 trade name]. The health care provider will continue the tests during your treatment.

Speak with your health care provider straightaway if you:

- feel unusually tired
- lose your appetite
- get nausea (feel sick)
- have yellowing of your skin or the white parts of your eyes
- pass dark urine
- pass stools that are clay-coloured (or are red or black)
- have belly pain, usually on the right side and near the chest

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 will also check your ECG during your treatment. Your health care provider may adjust your treatment if ECG abnormalities occur. In addition, you will have blood tests to check your levels of potassium, calcium and magnesium.

#### **Children and adolescents**

[TB397 trade name] is not recommended for children and adolescents younger than 14 years 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: 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
- ritonavir: a medicine used for HIV infection

#### **[TB397 trade name] with food and drink**

You should take [TB397 trade name] with food.

### **[TB397 trade name] with alcohol**

Avoid drinking alcohol while being treated with [TB397 trade name] since this increases 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.

It is not known if 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.

### **Driving and using machines**

[TB397 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

### **This medicine contains lactose monohydrate**

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.

This medicine may contain traces of cow's milk proteins. If you are allergic to cow's milk, 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 told you. Check with your health care provider if you are not sure.

[TB397 trade name] is used only in combination with linezolid and bedaquiline, and sometimes also with moxifloxacin. You must also read the package leaflets for these medicines. If you have any questions, ask your health care provider.

### ***Adults and adolescents 14 years and older***

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 further 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 all your TB medicines need to be interrupted, ask your health care provider how to complete the full course. 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 feeling tired, weak, thirsty, breathlessness and losing consciousness.
- blood tests showing increased levels of liver enzymes called
  - GGT (indicating how well your liver is working)
  - transaminase such as ALT, ASTThis may be a sign of liver injury. Tell your health care provider if you lose your appetite, get nausea (feel sick), feel unusually tired, have yellowing of your skin or the white parts of your eyes, pass dark urine, pass stools that are clay-coloured (or are red or black), or have belly pain, usually on the right side and near the chest.

*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  
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)

- headache
- feeling sick (nausea), being sick (vomiting), indigestion
- abdominal (belly) pain
- acne, itching skin, rash
- decreased appetite
- nerve problems in the hands or feet, such as pain, burning, abnormal sensation or numbness
- muscle and bone pain, such as joint pain, back pain, muscle pain
- blood tests indicating liver injury or problems with your pancreas

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

- sleeping difficulties
- weakness, fatigue
- taste disturbance
- dizziness
- muscle spasm
- diarrhoea, constipation
- inflammation of stomach lining (gastritis), pancreas inflammation
- stomach content flowing back up in the food pipe (oesophagus)
- hair loss, dry skin
- irritation or pain of the eye, vision problems
- optic nerve damage, inflammation with swellings and visual disturbances or both

- QT prolongation - a condition with certain abnormalities in the electrocardiogram (ECG, electrical recording of the heart)
- blood tests showing decreased blood sugar level

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

- fungal infection (including candida and yeast) in the mouth or throat, which appears as white patches and fungal infection elsewhere in the body
- too much fluid loss, reduced body fluid
- anxiety, depression
- enlarged liver, excessive bilirubin which can cause yellowing of the skin, and whites of the eyes (jaundice)
- eye lens disorder, dry eye
- 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
- muscles and skeleton stiffness
- 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 a reduced number of white blood cells (cells that help the body to fight infections), red blood cells (cells that transport oxygen) or blood platelets (cells that help the blood to clot)  
This can result in infections, paleness and tiredness, or abnormal bruising and bleeding
- blood tests showing decreased levels of
  - calcium
  - magnesium

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]**

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 label after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice 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 excipients; Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, sodium lauryl sulfate, povidone, colloidal silicon dioxide, 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

[TB397 trade name] is 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.

[TB397 trade name] is available in cartons of 10 x 10 or 12 x 10 tablets.

## Supplier and Manufacturer

### *Supplier*

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade,  
Marol Church road,  
Andheri (East),  
Mumbai – 400 059,  
India  
Tel: +91-22-66762800  
Fax: +91 -22-28216599  
e-mail:exports@macloedspharma.com

### *Manufacturer*

Macleods Pharmaceuticals Limited,  
Plot No.50 to 54A,  
SEZ, Phase II,  
Pithampur, Dist.: Dhar  
Madhya Pradesh, 454774,  
India  
Tel:+91-7292-350600  
Fax:+91-7292350603  
e-mail: nishata@macloedspharma.com

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

**This leaflet was last revised in November 2024**

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