

# Pretomid 200

Pretomanid Tablets 200mg

## What is in this leaflet?

1. What Pretomid Tablets are used for
2. How Pretomid Tablets works
3. Before you use Pretomid Tablets
4. How to use Pretomid Tablets
5. While you are using Pretomid Tablets
6. Side effects
7. Storage and Disposal of Pretomid Tablets
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

## **1. WHAT PRETOMID TABLETS ARE USED FOR:**

The combination regimen of Pretomid Tablets, bedaquiline, and linezolid includes three prescription antibiotics that are used together in adults to treat tuberculosis (TB) of the lungs that is extensively drug resistant (XDR) or who cannot tolerate or do not respond to treatment for multi drug - resistant (MDR) TB.

Pretomid Tablets are not for use in people who have:

- TB that is not resistant to antibiotics.
- an inactive (latent) TB infection.
- a type of TB other than TB of the lungs.
- MDR TB who can tolerate or who respond to medicines usually used to treat MDR TB.

It is not known if Pretomid Tablets are safe and effective for use except in combination with bedaquiline and linezolid as part of the recommended dosing regimen.

It is not known if Pretomid Tablets are safe and effective in children.

## **2. HOW PRETOMID TABLETS WORKS:**

Pretomid Tablets are a prescription medicine used as part of a combination regimen with bedaquiline and linezolid.

## **3. BEFORE YOU USE PRETOMID TABLETS:**

*When you must not use it*

**Do not take the combination regimen of Pretomid Tablets, bedaquiline, and linezolid if:**

- you have been told by your healthcare provider not to take bedaquiline or linezolid.
- You should not drink alcohol while taking the combination regimen of Pretomid Tablets, bedaquiline, and linezolid.

### Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Pregnancy**

If you are pregnant or plan to become pregnant. It is not known if Pretomid will harm your unborn baby. Talk to your healthcare provider about the possible risks to your baby if you take the combination regimen of Pretomid Tablets, bedaquiline, and linezolid while you are pregnant.

### **Breast-feeding**

If you are breastfeeding or plan to breastfeed. It is not known if pretomanid passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take the combination regimen of Pretomid Tablets, bedaquiline, and linezolid.

*Before you start to use it*

**Before you take the combination regimen of Pretomid Tablets, bedaquiline, and linezolid, tell your healthcare provider about all of your medical conditions, including if you:**

- have liver problems.
- have kidney problems.
- have or have had an abnormal heart rhythm (ECG) or other heart problems, including heart failure. have a family history of a heart problem called “congenital long QT syndrome.” have decreased thyroid gland function (hypothyroidism).
- have HIV infection.
- have been told that you have low levels of calcium, magnesium or potassium in your blood.
- have ever had a seizure.

### Taking other medicines:

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. You should not take herbal products or medicines that can harm your liver during treatment with the combination regimen of Pretomid Tablets, bedaquiline, and linezolid.

The combination regimen of Pretomid Tablets, bedaquiline, and linezolid regimen may affect how other medicines work, and other medicines may affect how the combination regimen of Pretomid Tablets, bedaquiline, and linezolid works.

Especially tell your healthcare provider if you take:

- a type of medicine called a CYP3A4 inducer, such as efavirenz or rifampin. Ask

# Pretomid 200

Pretomanid Tablets 200mg

your healthcare provider if you are not sure.

## 4. HOW TO USE PRETOMID TABLETS:

### How much to use

Pretomid Tablets, bedaquiline, and linezolid can be taken together.

Swallow Pretomid Tablets whole with water.

Take Pretomid Tablets, bedaquiline, and linezolid with food.

### **Week 1 and Week 2:**

Take 200 mg of Pretomid Tablets (1 tablet), 400 mg of bedaquiline, and 1,200 mg of linezolid 1 time each day.

### **Week 3 to Week 26:**

Take 200 mg of Pretomid Tablets (1 tablet) and 1,200 mg of linezolid 1 time each day.

Take 200 mg of bedaquiline 3 times a week.

- Take your doses of bedaquiline at least 48 hours apart. For example, you may take bedaquiline on Monday, Wednesday, and Friday every week from Week 3 to Week 26. You may need to take the combination regimen of Pretomid Tablets, bedaquiline, and linezolid for longer than 26 weeks. Talk with your healthcare provider. If your healthcare provider tells you to stop taking the combination regimen of Pretomid Tablets, bedaquiline, and linezolid for a period of time, follow the instructions given to you by your healthcare provider for taking the missed doses at the end of your treatment.

### When to use it:

Pretomid Tablets must only be taken with bedaquiline and linezolid as part of the dosing regimen prescribed by your healthcare provider.

Take the combination regimen of Pretomid Tablets, bedaquiline, and linezolid exactly as your healthcare provider tells you to take it.

It is important that you complete the full course of treatment with the combination regimen of Pretomid Tablets, bedaquiline, and linezolid, and not miss any doses, even if you feel better before you have completed the full course of treatment. Missing doses may decrease the effectiveness of the treatment and increase the chance that your TB will not be treatable by the combination regimen of Pretomid Tablets, bedaquiline, and linezolid or other medicines.

### How long to use it:

Take the combination regimen of Pretomid Tablets, bedaquiline, and linezolid for a total of 26 weeks.

- Your healthcare provider will tell you if you should take the combination regimen of Pretomid Tablets, bedaquiline, and linezolid for longer than 26 weeks.
- Your healthcare provider will tell you if you should stop taking linezolid before you have taken it for 26 weeks or if you should reduce your dose of linezolid due to side effects.

Your healthcare provider or caregiver will watch you take your doses of Pretomid Tablets, bedaquiline, and linezolid.

### If you forget to take Pretomid Tablets:

-Do not miss a dose of Pretomid Tablets, bedaquiline, or linezolid unless instructed to do so by your healthcare provider. If you miss doses or do not

complete the total 26 weeks of treatment, your treatment may not work as well, and your TB may be harder to treat.

- If your healthcare provider tells you to stop taking the combination regimen of Pretomid tablets, bedaquiline, and linezolid for a period of time, follow the instructions given to you by your healthcare provider for taking the missed doses at the end of your treatment. You should not make up any missed doses of linezolid alone that your healthcare provider told you not to take due to side effects.
- If you miss a dose of Pretomid tablets, bedaquiline, or linezolid and you are not sure what to do, talk to your healthcare provider as soon as possible.

### If you take Pretomid Tablets too much (Overdose):

If you take too much Pretomid Tablets, go to the nearest hospital emergency room right away.

### If you stop taking Pretomid Tablets

Do not stop taking Pretomid Tablets, bedaquiline, or linezolid without first talking to your healthcare provider.

## 5. WHILE YOU ARE USING PRETOMID:

- *Things you must do*

Pretomid Tablets should be swallowed whole and not chewed or crushed.

Tell your doctor immediately if you become pregnant while taking this medication.

# Pretomid 200

Pretomanid Tablets 200mg

- Things you must not do

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Pretomid Tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of:

Driving and using machines:

Pretomanid may have a minor influence on the ability to drive and use machines. Dizziness has been reported in some patients taking Pretomanid and some patients experienced visual impairment. This should be considered when assessing a patient's ability to drive or operate machinery.

## 6. SIDE EFFECTS

The combination regimen of Pretomid Tablets, bedaquiline, and linezolid may cause serious side effects including:

**Liver problems.** Your healthcare provider should do blood tests to check your liver at least before you start taking the combination regimen of Pretomid Tablets, bedaquiline, and linezolid, 2 weeks after starting treatment, and then monthly during treatment. Tell your healthcare provider right away if you have symptoms of liver problems, such as:

- unusual tiredness
- loss of appetite
- nausea
- yellowing of your skin or the whites of your eyes
- dark (tea-colored) urine
- tenderness in the upper right side of your stomach-area (abdomen)

**Low blood cell counts.** The combination regimen of Pretomid Tablets, bedaquiline, and linezolid can cause low red blood cell counts (anemia), low white blood cell counts (leukopenia), low blood platelet

counts (thrombocytopenia) or a combination of low red and white blood cell counts and low blood platelet counts (pancytopenia). Low blood cell counts are a side effect of linezolid. Anemia is a common side effect of linezolid, but can be serious and life-threatening. Low blood cell counts were reversible when linezolid treatment was reduced, stopped for a period of time, or stopped permanently. Your healthcare provider should check your blood cell counts at least before you start taking the combination regimen of Pretomid Tablets, bedaquiline, and linezolid, 2 weeks after starting treatment, and then monthly during treatment.

**Nerve problems** in your arms, hands, legs, and feet (peripheral neuropathy). The combination regimen of Pretomid Tablets, bedaquiline, and linezolid can cause nerve problems in your arms, hands, legs, and feet. Tell your healthcare provider if you have symptoms of nerve problems in your arms, hands, legs, or feet, including:

- numbness
- burning
- a feeling of "pins and needles"
- tremors
- problems with balance
- weakness

**Vision problems.** The combination regimen of Pretomid Tablets, bedaquiline, and linezolid can cause nerve problems in your eyes (optic neuropathy). Nerve problems in your eyes can cause problems with your vision. Tell your healthcare provider right away if you have symptoms of nerve problems in your eyes, such as changes in vision.

**Heart rhythm problem called QT prolongation.**

The combination regimen of Pretomid Tablets, bedaquiline, and linezolid can cause a heart rhythm problem. Heart rhythm problem is a side effect of bedaquiline. Your healthcare provider should do a test called an electrocardiogram (ECG) to check your heart before you start taking the combination regimen of Pretomid Tablets, bedaquiline, and linezolid and at least 2, 12, and 24 weeks after starting treatment. Tell your healthcare provider right away if you:

- have a change in heartbeat (a fast or irregular heartbeat)
- feel dizzy or faint.

**Effects on male fertility.** It is not known if pretomanid can cause fertility problems in males. This could affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.

**Build-up of an acid in your blood (lactic acidosis).**

The combination regimen of Pretomid Tablets, bedaquiline, and linezolid can cause a build-up of acid in your blood. A build-up of acid in your blood is a side effect of linezolid. Call your healthcare provider right away if you have nausea and vomiting that keep coming back.

The most common side effects of the combination regimen of Pretomid Tablets, bedaquiline, and linezolid include: Acne, nausea, vomiting, muscle and bone pain, headache, abnormal blood tests that may be due to injury to your liver, heartburn, decreased appetite, rash, itching, stomach area (abdominal) pain, chest pain that worsens when you breathe or cough, lower respiratory tract infection, abnormal blood tests

# Pretomid 200

Pretomanid Tablets 200mg

that may be due to injury to your liver, heartburn, decreased appetite, rash, itching, stomach area (abdominal) pain, chest pain that worsens when you breathe or cough, lower respiratory tract infection, abnormal blood tests that may be due to injury to your pancreas, coughing up blood, cough, low blood sugar, unusual weight loss, diarrhea. These are not all the possible side effects of the combination regimen of Pretomid Tablets, bedaquiline, and linezolid. For more information, ask your healthcare provider or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## 7. STORAGE AND DISPOSAL OF PRETOMID TABLETS:

### Storage

Store below 30°C. Protect from light

Keep this medicine out of the sight and reach of children

### Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 8. PRODUCT DESCRIPTION What it looks like and contents of the pack

### -What Pretomid looks like

Pretomid uncoated tablets are White to off white, oval shaped, biconvex, uncoated tablets debossed with "K31" on one side and plain on other side.

Available in Cold Form  
Alu/Alu Blister Pack of 10 tablets.

Available in pack size of 12 x 10's tablets and 10 x 10's tablets

## What Pretomid Tablets contains

### Active ingredient:

- Pretomanid

### Inactive ingredients

- colloidal silicon dioxide,
- lactose monohydrate,
- magnesium stearate,
- microcrystalline cellulose,
- povidone,
- sodium lauryl sulfate,
- sodium starch glycolate
- Purified water

**MAL No:** MAL25086001AZ

## 9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER MANUFACTURER:

**MACLEODS PHARMACEUTICALS LTD.**  
Plot No.M-50 to M-54A,  
Indore Special Economic Zone,  
Phase II,  
Pithampur, Dist.: Dhar,  
Madhya Pradesh 454774, India (IND)  
Office: Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai-400059,India

## PRODUCT REGISTRATION HOLDER:

**Macleods Pharmaceutical Sdn. Bhd.,**  
A2-27-1 Soho Suites KLCC,  
Jalan Perak, 50450 Kuala Lumpur, Malaysia.

**10.Date of revision:**  
11/02/2026

**11.Serial Number**  
NPRA (R1) 24/045