

<i>Applicant/PHCR:</i>	Macleods Pharmaceuticals SA (Pty) Ltd
<i>Product Proprietary Name:</i>	Terizidone Macleods 250 mg Capsules
<i>Active Ingredient:</i>	Terizidone
<i>Dosage Form:</i>	Capsules
<i>Date:</i>	31 January 2023

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

TERIZIDONE MACLEODS 250 mg CAPSULES

Sugar free

Read all of this leaflet carefully before you start taking TERIZIDONE MACLEODS 250 mg CAPSULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or other health care provider.
- **TERIZIDONE MACLEODS 250 mg CAPSULES** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **TERIZIDONE MACLEODS 250 mg CAPSULES** is and what it is used for
2. What you need to know before you take **TERIZIDONE MACLEODS 250 mg CAPSULES**
3. How to take **TERIZIDONE MACLEODS 250 mg CAPSULES**
4. Possible side effects
5. How to store **TERIZIDONE MACLEODS 250 mg CAPSULES**
6. Contents of the pack and other information

1. What **TERIZIDONE MACLEODS 250 mg CAPSULES** is and what it is used for

Multidrug-resistant tuberculosis (MDR-TB) treatment in combination with other antimycobacterial medicine to treat tuberculosis when other first-line TB medicines did not help.

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2. What you need to know before you take TERIZIDONE MACLEODS 250 mg CAPSULES

It is important that you tell your doctor or healthcare professional if you suffer from any of the conditions mentioned below, if you are taking TERIZIDONE MACLEODS 250 mg CAPSULES or have been prescribed TERIZIDONE MACLEODS 250 mg CAPSULES.

Do not take TERIZIDONE MACLEODS 250 mg CAPSULES

- If you are hypersensitive (allergic) to terizidone, cicloserin or to any of the other ingredients of **TERIZIDONE MACLEODS 250 mg CAPSULES** (listed in section 6).
- If you have severe kidney disease.
- If you have epilepsy.
- If you suffer from depression, anxiety or other mental illness.
- If you suffer from chronic alcoholism.
- If you suffer from porphyria.

Warnings and precautions

Take special care with **TERIZIDONE MACLEODS 250 mg CAPSULES**

- Your doctor will monitor your blood levels of the active medicine in **TERIZIDONE MACLEODS 250 mg CAPSULES** on a regular basis to ensure you are receiving the correct dose that will minimise adverse reactions such as feeling depressed, anxious, confused, disorientated, aggressive, irritable, paranoid (unfounded or exaggerated distrust of others), dizziness, vertigo (spinning sensation), drowsiness, headache, problems with speech, tremor, muscle twitching or trembling, numbness, tingling or burning pain and weakness in the hands or feet.
- **TERIZIDONE MACLEODS 250 mg CAPSULES** will only be prescribed to you in combination with other medicines for the treatment of TB.
- Large doses or drinking alcohol when taking this medicine would cause some side effects such as fits or seizures to occur more readily.
- If **TERIZIDONE MACLEODS 250 mg CAPSULES** causes you to feel very depressed or to have thoughts of suicide, check with your doctor immediately.
- If you experience any skin reactions, stop taking **TERIZIDONE MACLEODS 250 mg CAPSULES**

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and check with your doctor immediately.

- Your doctor may prescribe Vitamin B6 (pyridoxine) with **TERIZIDONE MACLEODS 250 mg CAPSULES** to minimise adverse reactions such as dizziness, drowsiness or neuropathy (damage to the nerves resulting in poor coordination, muscle weakness, pain in the fingers or toes, or numbness).
- Your doctor will perform regular blood tests, liver and kidney function tests while you are taking **TERIZIDONE MACLEODS 250 mg CAPSULES**.
- If you have mild to moderate kidney disease, your doctor will prescribe a lower dose.

Other medicines and TERIZIDONE MACLEODS 250 mg CAPSULES

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

When you are taking **TERIZIDONE MACLEODS 250 mg CAPSULES**, it is especially important to tell your doctor or healthcare professional if you are taking any other medicine and especially:

- Alcohol
- cicloserin – a medicine used in the treatment of tuberculosis (TB) or other serious infections
- ethionamide - a medicine used in the treatment of tuberculosis (TB)
- isoniazid– a medicine used in the treatment of tuberculosis (TB).

TERIZIDONE MACLEODS 250 mg CAPSULES with food or drink

TERIZIDONE MACLEODS 250 mg CAPSULES can be taken with or without meals. Avoid alcohol. Excessive alcohol ingestion may cause convulsions (fits).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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TERIZIDONE MACLEODS 250 mg CAPSULES should not be taken during pregnancy and breastfeeding.

Driving and using machines

TERIZIDONE MACLEODS 250 mg CAPSULES may cause anxiety, disorientation, confusion, dizziness and drowsiness. If you experience the above while taking **TERIZIDONE MACLEODS 250 mg CAPSULES** you should not drive or use any tools or machines.

3. How to take TERIZIDONE MACLEODS 250 mg CAPSULES

Do not share medicines prescribed for you with any other person.

Always take or give **TERIZIDONE MACLEODS 250 mg CAPSULES** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Adults:

The usual dose is one **TERIZIDONE MACLEODS 250 mg CAPSULE** every 6 – 8 hours for as long as prescribed by your doctor.

The capsule should be swallowed whole with a glass of water.

If you have the impression that the effect of **TERIZIDONE MACLEODS 250 mg CAPSULES** is too strong or too weak, talk to your doctor or pharmacist.

If you take more TERIZIDONE MACLEODS 250 mg CAPSULES than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control center.

Too much **TERIZIDONE MACLEODS 250 mg CAPSULES** can increase the intensity of side effects.

If you forget to take TERIZIDONE MACLEODS 250 mg CAPSULES

If you have missed a dose of **TERIZIDONE MACLEODS 250 mg CAPSULES**, take it as soon as you remember. However if it is almost time for your next dose, skip the missed dose and go back to your regular scheduling. Never double your dose.

If you stop taking TERIZIDONE MACLEODS 250 mg CAPSULES

Do not stop taking TERIZIDONE MACLEODS 250 mg CAPSULES because you feel better.

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If the full treatment prescribed by your doctor is not completed, some of the bacteria causing the TB infection may not be killed. These bacteria may continue to grow and multiply so the TB infection may not clear completely or it may return.

4. Possible side effects

TERIZIDONE MACLEODS 250 mg CAPSULES can have side effects.

Not all side effects reported for **TERIZIDONE MACLEODS 250 mg CAPSULES** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **TERIZIDONE MACLEODS 250 mg CAPSULES**, please consult your health care provider for advice.

If any of the following happens, stop taking **TERIZIDONE MACLEODS 250 mg CAPSULES** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of face, tongue or throat with difficulties in swallowing and breathing
- hives and severe skin reactions that can include blistering of the skin.

These are all very serious side effects. If you have them you may have had a serious allergic reaction to **TERIZIDONE MACLEODS 250 mg CAPSULES**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you experience any of the following:

- mental illness with thoughts of committing suicide
- coma (losing consciousness for longer than 6 hours)
- having seizures (fits)
- heart failure (disease of the heart with shortness of breath, and swelling of the feet or legs due to fluid build-up).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects and they worry you or if any of these symptoms are severe or do not go away:

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- feeling depressed, anxious, confused, disorientated, aggressive, irritable, paranoid (unfounded or exaggerated distrust of others), mania (mood of excitement, over-activity and uninhibited behaviour)
- dizziness, vertigo (spinning sensation), drowsiness, headache, problems with speech, tremor, muscle twitching or trembling, numbness, tingling or burning pain, weakness in the hands or feet
- stomach irritation
- laboratory tests may show:
 - increased liver enzymes
 - larger than normal red blood cells due to folic acid and vitamin B12 deficiency or red blood cells which do not develop normally leading to anaemia
 - increased sensitivity of the skin to sunlight.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **TERIZIDONE MACLEODS 250 mg CAPSULES**.

5. How to store TERIZIDONE MACLEODS 250 mg CAPSULES

Store at or below 25 °C in a dry place.

Keep the blister in the carton until required for use.

Keep the container closed.

Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.

Do not dispose of unused medicines in drains or sewerage systems e.g. toilets

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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6. Contents of the pack and other information

What TERIZIDONE MACLEODS 250 mg CAPSULES contains

The active substance is terizidone 250 mg.

Sugar free.

The other ingredients are: microcrystalline cellulose, disodium edetate, hypromellose, stearic acid, hard gelatine capsule containing gelatine, sodium methyl paraben, sodium propyl paraben, sodium lauryl sulphate, titanium dioxide (CI No. 77891), brilliant blue (CI No. 42090) and carmoisine (CI No. 14720).

What TERIZIDONE MACLEODS 250 mg CAPSULES looks like and contents of the pack

Blue colour cap and blue colour body size "0" hard gelatine capsule containing white to off white granules.

Alu-Alu strip pack:

Silver-coloured, printed aluminium foil laminated with 150 gauge polyethylene (soft tempered) and silver-coloured, plain aluminium foil laminated with 150 gauge polyethylene (soft tempered) packed in a pre-printed unit carton. Pack size: 100's (10 x 10).

HDPE container pack:

150 ml round, white, heavy weight HDPE with 38 mm neck finish closed with 38 mm white continuous thread polypropylene closure with pulp and heat seal 123 white printed liner packed in a pre-printed carton. Pack size: 100 tablets.

7. Holder of Certificate of Registration

MACLEODS PHARMACEUTICALS SA (PTY) LTD.

Office Block 1, Bassonia Estate Office Park (East),

1 Cussonia Drive, Bassonia Rock, Ext. 12,

Alberton, South Africa.

This leaflet was last revised in

06/03/2023

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