PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Terizidone 250 mg capsules[1]

Terizidone

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 any further questions, 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 are the same as yours.
- If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT TERIZIDONE 250 MG CAPSULES IS AND WHAT IT IS USED FOR

Terizidone 250 mg capsules is used to treat tuberculosis (TB) caused by *Mycobacterium tuberculosis*. It is always given together with other medicines for TB. Terizidone, the active ingredient of Terizidone 250 mg capsules, belongs to the family of medicines called antibiotics.

To help clear up your tuberculosis (TB) completely, you must keep taking this medicine for the full time of treatment, even if you begin to feel better. This is very important. It is also important that you do not miss any doses.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TERIZIDONE 250 MG CAPSULES

Do not take Terizidone 250 mg capsules:

- if you are allergic to terizidone, cycloserine or any of the other ingredients of Terizidone 250 mg capsules (see section 6, What Terizidone 250 mg capsules contains),
- if you have seizures (epilepsy),
- if you have a psychiatric disorder (e.g. depressions or anxiety disorder),
- if you drink alcohol regularly.

Warnings and precautions

Terizidone 250 mg capsules may severely affect your mind and nervous system (see “Possible side effects”). Your health care provider will regularly check for these symptoms. If you or your contacts notice any undue depression or personality change while you are taking terizidone, report this immediately to your health care provider.

If you experience rash or yellowing of the skin and eyes (possible signs of an allergic reaction), tell your health care provider immediately.

1 Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Discuss the use of Terizidone 250 mg capsules with your health care provider if you have kidney disease. Your health care provider may need to adjust your dose.

It is important that your health care provider knows about all your symptoms even when you think they are not related to tuberculosis infection.

Other medicines and Terizidone 250 mg capsules

Tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. These may affect the action of Terizidone 250 mg capsules, or Terizidone 250 mg capsules may affect their action.

Concurrent use of Terizidone 250 mg capsules with isoniazid or ethionamide (other antituberculosis medicines) may make the side effects on the central nervous system worse. Your health care provider may adjust the dosage of the antituberculosis medicines and will regularly check for these side effects.

Terizidone 250 mg capsules with food, drink and alcohol

Do not take Terizidone 250 mg capsules with a high-fat meal. The absorption of terizidone may be negatively affected. Terizidone should best be taken without food. It can be taken with orange juice

Do not drink alcohol while taking Terizidone 250 mg capsules. You are more likely to experience serious side effects such as seizures if you drink alcohol while taking this medicine. Also, alcohol may make side effects of terizidone such as dizziness and drowsiness more severe (see “Do not take Terizidone 250 mg capsules”).

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, you must contact your health care provider to discuss the potential benefits and risks of your tuberculosis therapy to you and your child.

Terizidone passes into the breast milk. However, no negative effects have been reported in breast-fed-infants, whose mothers were receiving terizidone. If the infant is breastfed both the breast feeding mother and the infant should be dosed with Vitamin B6.

Driving and using machines

Terizidone 250 mg capsules may cause side effects such as dizziness or drowsiness, that can impair your ability to drive and to use machines.

Terizidone 250 mg capsules contains sodium methyl paraben, sodium propyl paraben and carmoisine

This medicinal product contains sodium methyl paraben, sodium propyl paraben and carmoisine, which may cause allergic reactions.

3. HOW TO TAKE TERIZIDONE 250 MG CAPSULES

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Your health care provider will assign the dose of Terizidone 250 mg capsules appropriate for you. The following information includes only the average doses of this medicine. If your prescribed dose is different, do not change it unless your health care provider tells you to do so.

Adults:
The usual dose is 10-15 mg/kg/day, max. 1000 mg/day given in two divided doses every 12 hours or once a day if tolerated.

Body weight	30-55.9 kg	56-70kg	≥71kg
Daily dose	500 mg	750 mg	1000 mg
Number of capsules per day	2	3	4

This dose is either split up to be taken twice daily (in the morning and evening) or once daily if tolerated.

Children:
For children the dose will be determined by the health care provider that prescribes the drug. Doses of 10-20 mg per kilogram of body weight per day have been used (daily maximum 1000 mg).

The recommended dose for children with a body weight of 23-30 kg is 250 mg terizidone (1 capsule) twice daily. For children who cannot swallow capsules, the capsules can be opened and dissolved in 10 ml water to aid administration.

For children weighing less than 23 kg an extemporaneous formulation for the administration of fractional doses has to be prepared from the 250mg capsule as follows:

The contents of one capsule should be dissolved in 10 ml drinking water and the weight-adjusted dose should then be withdrawn by use of an oral syringe with 0.25 ml markings as per the following dosing table.

Body weight	5 kg	6-9.9 kg	10-11.9 kg	12-22.9 kg
Dose (every 12 hours)	1.25 ml (31.25 mg)	2.5 ml (62.5mg)	3.75 ml (93.75 mg]	5 ml (125 mg)

The dose should be administered immediately and the remaining mixture should be discarded.

Pyridoxine (Vitamin B6) should be taken concomitantly with terizidone. If the mother is breastfeeding her infant, the infant should also be dosed with Vitamin B6.

Terizidone 250 mg capsules will always be taken in combination with other medicines against tuberculosis; please make sure to follow the instructions within the supplied package leaflet(s).

If you take more Terizidone 250 mg capsules than you should

If you have taken too many tablets you may develop headaches, dizziness, confusion, drowsiness, hyper-irritability, numbness or tingling in your hands or feet, slurred speech and personality changes (psychosis). You should immediately contact your health care provider or the nearest hospital emergency department for further advice.

If you forget to take Terizidone 250 mg capsules

Take the missed dose as soon as possible, unless your next dose is scheduled in less than six hours.
Skip the missed dose if it is almost time for your next regular dose.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Terizidone 250 mg capsules

Do not stop treatment unless your health care provider tells you to, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Terizidone 250 mg capsules can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Terizidone 250 mg capsules, and those caused by any other medicines you may be taking at the same time, or by the disease itself.
For this reason, it is important that you inform your health care provider of any change in your health.

The most *commonly* reported (greater than 1 in every 100 patients treated) side effects are:

- confusion or abnormal behaviour,
- depression
- lethargy
- nervousness
- numbness or tingling in your hands or feet,
- tremors (shaking),
- drowsiness,
- dizziness,
- difficulty speaking,
- irritability,
- headache.

There are *rare* reports (between 1 in 10 000 and 1 in 1000 patients treated) of:

- allergic reactions (difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; skin rash or hives, increased light sensitivity of the skin or inflammation of the liver).
- irregular heart beat and sudden development of heart failure (your heart muscle doesn't pump blood as well as it should) in patients receiving 1 g or more per day.

Frequency estimates for the following effects are not available:

- vitamin B12 deficiency, folic acid deficiency, potentially leading to anaemia, which is characterized by many large immature and dysfunctional red blood cells (megaloblasts), other forms of anaemia.
- elevated liver enzymes, particularly in patients with pre-existing liver disease.
- involuntary rhythmic jerking movements of the arms and legs (clonic seizures), convulsion, coma, slight or partial paralysis, extremely high fever
- skin rash, which can be life-threatening and also involve the mucous membranes (Stevens-Johnson syndrome)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider as soon as possible. You can also report side effects directly via the local reporting system.

5. HOW TO STORE TERIZIDONE 250 MG CAPSULES

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

Do not store above 25°C. Store in a dry place, protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via 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 Terizidone 250 mg capsules contains

The active ingredient is 250 mg terizidone.

The other ingredients are:

Capsule fill:
Microcrystalline cellulose
Disodium edetate
Hypromellose
Stearic acid

Capsule shell:
Gelatin
Sodium methyl paraben
Sodium propyl paraben
Sodium lauryl sulphate
Titanium dioxide
Brilliant blue
Carmoisine

What Terizidone 250 mg capsules looks like and contents of the pack

Terizidone 250 mg capsules is a blue colour cap and blue colour body size “0” hard gelatin capsule containing creamy coloured granular powder.

Strip packs
10 capsules are packed in a printed aluminium foil laminated with 150 gauge polyethene, such 10 strips are further packed in a carton.

Bottle packs
Round, white, HW-HDPE, 150cc, 38 – neck with continuous thread closure with pulp and HS 123 white printed liner, 38 mm with polypropylene cap. Pack size: 100 capsules.

Supplier and Manufacturer

Supplier	**Manufacturer**
Macleods Pharmaceuticals Limited 304, Atlanta Arcade Marol Church road Andheri (East) Mumbai – 400 059 India Tel: +91-22-66762800 Fax: +91 -22-28216599	Macleods Pharmaceuticals Limited Unit II, Plot No. 25 – 27, Survey No. 366 Premier Industrial Estate Kachigam Daman – 396210 India Tel: +91-260-2240125 Fax: +91-260-2241565

For any information about this medicine, contact the supplier.

This leaflet was last approved in April 2018

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