

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING HDPE bottle**

**1. NAME OF THE MEDICINAL PRODUCT**

Terizidone 250mg Capsules<sup>1</sup>

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each capsule contains 250 mg of terizidone.

**3. LIST OF EXCIPIENTS**

Contains sodium methyl paraben, sodium propyl paraben and carmoisine

See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

100 hard capsules

**5. METHOD AND ROUTE OF ADMINISTRATION**

Oral use

Read the patient information leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP {MM/YYYY}

<sup>1</sup> 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.

**9. SPECIAL STORAGE CONDITIONS**

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

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE SUPPLIER**

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

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

TB303

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

**14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Strip carton**

**1. NAME OF THE MEDICINAL PRODUCT**

Terizidone 250mg Capsules

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each capsule contains 250 mg of terizidone.

**3. LIST OF EXCIPIENTS**

Contains sodium methyl paraben, sodium propyl paraben and carmoisine

See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

100 (10 x10) hard capsules

**5. METHOD AND ROUTE OF ADMINISTRATION**

Oral use  
Read the patient information leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

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

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

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**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

TB 303

**13. MANUFACTURER'S BATCH NUMBER**

<BN> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

Terizidone 250 mg capsules

**2. NAME OF THE SUPPLIER**

Macleods Pharmaceuticals Ltd

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

BN {number}