

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB397 trade name]* Pretomanid 200 mg tablets
Pretomanid

2. Statement of active substance

Each tablet contains 200 mg of pretomanid

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Uncoated tablet
10 x 10 tablets
12 x 10 tablets

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 this medicine 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 30°C.

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

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Marol Church Road
Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

[TB397 trade name]

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Aluminium/aluminium blisters

1. Name of the medicinal product

[TB397 trade name] Pretomanid 200 mg tablets
Pretomanid

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other