

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 uncoated tablet contains 200 mg of Pretomanid

3. List of excipients

Contains lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Uncoated tablets

10 x10

12 x10

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

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

**Special precautions for disposal of unused medicinal products or waste materials derived from
such medicinal products, if appropriate**

None

10. Name and address of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059,
India

11. WHO Reference Number (Prequalification Programme)

[TB397 trade name]

12. Manufacturer's batch number

<Batch> <Lot> {number}

13. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

14. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Aluminium/aluminium blisters

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[TB397 trade name] Pretomanid 200 mg tablets

Pretomanid

2. Name of the supplier

Macleods Pharmaceuticals Limited
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Marol Church road,
Andheri (East),
Mumbai – 400 059,
India

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other