

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB403 trade name]* Pretomanid 200 mg tablets

Pretomanid

2. Statement of active substance

Each tablet contains 200 mg Pretomanid

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Uncoated tablets

26 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

Store at a temperature below 30°C. Protect from moisture.

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

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

11. Name and address of the supplier

Lupin Limited
Kalpataru Inspire, 3rd Floor
Off Western Express Highway
Santacruz (East)
Mumbai – 400055
India

12. WHO Reference Number (Prequalification Programme)

TB403

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[TB403 trade name][†] Pretomanid 200 mg tablets

Pretomanid

2. Statement of active substance

Each tablet contains 200 mg Pretomanid

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Uncoated tablets

10 x 10 tablets

12 x 10 tablets

6 x 14 tablets

12 x 14 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

Store at a temperature below 30°C. Protect from moisture.

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

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

11. Name and address of the supplier

Lupin Limited
Kalpataru Inspire, 3rd Floor
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12. WHO Reference Number (Prequalification Programme)

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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

PVC/PVDC on aluminium

1. Name of the medicinal product

[TB403 trade name] Pretomanid 200 mg tablets

Pretomanid

2. Name of the supplier

Lupin Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other