

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB333 trade name]* Ethionamide 125 mg Dispersible Tablets

Ethionamide

2. Statement of active substance

Each tablet contains 125 mg ethionamide.

3. List of excipients

Contains aspartame. See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

5 x 6 Tablets

10 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

Store below 30°C in dry place. Protect from light.

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

10. Name and address of the supplier

Macleods Pharmaceuticals Limited

304, Atlanta Arcade

Marol Church Road

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

Andheri (East)
Mumbai – 400 059
India
Tel: +91-22-66762800
Fax: +91 -22-28216599

11. WHO Reference Number (Prequalification Programme)

TB333

12. Manufacturer's batch number

<Batch> {number}

13. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

14. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON STRIPS

Aluminium/Aluminium strips

1. Name of the medicinal product

[TB333 trade name] Ethionamide 125 mg Dispersible Tablets
Ethionamide

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> <BN> {number}

5. Other