

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle label

1. Name of the medicinal product

[TB242 trade name]*

Ethionamide 250mg tablets

2. Statement of active substance

Each film-coated tablet contains 250 mg ethionamide.

3. List of excipients

Each tablet contains FD&C yellow #6/sunset yellow FCF aluminium lake.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablet.

100 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

Micro Labs Limited

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

31 Race Course Road
Bangalore 560 001
Karnataka
India

12. WHO Reference Number (Prequalification Programme)

TB242

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

Blister pack

1. Name of the medicinal product

[TB242 trade name]

Ethionamide 250mg tablets

2. Statement of active substance

Each film-coated tablet contains 250 mg ethionamide.

3. List of excipients

Each tablet contains FD&C yellow #6/sunset yellow FCF aluminium lake.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablet.

10 x 10 film-coated 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

Micro Labs Limited
31, Race Course Road
Bangalore 560 001

Karnataka
India

12. WHO Reference Number (Prequalification Programme)

TB242

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 OR STRIP

PVDC/PVC/Alu Blister

1. Name of the medicinal product

[TB242 trade name]

Ethionamide 250mg tablets

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other