

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
HDPE bottle

1. Name of the medicinal product

[TB304 trade name]*

Cycloserine 250 mg capsules

2. Statement of active substance

Each hard gelatin capsule contains 250 mg cycloserine

3. List of excipients

4. Pharmaceutical form and contents

Capsules

100 capsules

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 25°C, store in tight container Protect from moisture. Do not remove the desiccant canister.

Discard the product 30 days after initial opening.

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

Mylan Laboratories Limited
Plot No.564/A/22, Road No. 92, Jubilee Hills
Hyderabad – 500096

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

Telangana
India

12. WHO Reference Number (Prequalification Programme)

TB304

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 carton

1. Name of the medicinal product

[TB304 trade name]

Cycloserine 250 mg capsules

2. Statement of active substance

Each hard gelatin capsule contains 250 mg cycloserine

3. List of excipients

4. Pharmaceutical form and contents

Capsules

10 (1 x 10) capsules

100 (10 x 10) capsules

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 25°C, store in tight container Protect from moisture. Do not remove the desiccant canister.

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

Mylan Laboratories Limited
Plot No.564/A/22, Road No. 92, Jubilee Hills
Hyderabad – 500096
Telangana
India

12. WHO Reference Number (Prequalification Programme)

TB304

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

Blister

1. Name of the medicinal product

[TB304 trade name]

Cycloserine 250 mg capsules

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other