

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB330 trade name]* Cycloserine 125 mg capsules
Cycloserine

2. Statement of active substance

Each hard gelatin capsule contains 125 mg cycloserine

3. List of excipients

Contains FD&C yellow #6 (sunset yellow FCF)

4. Pharmaceutical form and contents

Hard gelatin capsule
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

Store in the original package below 25°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

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.
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Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

TB330

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

Aluminium blister/strip

1. Name of the medicinal product

[TB330 trade name] Cycloserine 125 mg capsules
Cycloserine

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other