

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB154 trade name]*

cycloserine 250 mg capsules

2. Statement of active substance

Each capsule contains 250 mg cycloserine.

3. List of excipients

Each capsule contains carmoisine, sunset yellow (FD&C YELLOW #6) and methyl and propyl paraben

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Capsule

9 x 10 capsules

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

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

11. Name and address of the supplier

Macleods Pharmaceuticals Ltd.
304, Atlanta Arcade,
Marol Church Road,
Andheri (East),
Mumbai 400 059,
India

12. WHO Reference Number (Prequalification Programme)

TB154

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

Alu/Alu strip and Alu/Alu cold form blister card

1. Name of the medicinal product

[TB154 trade name]

cycloserine 250 mg capsules

2. Name of the supplier

Macleods Pharmaceuticals Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other