

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB385 trade name]* Cycloserine 250 mg Capsules

Cycloserine

2. Statement of active substance

Each hard gelatin capsule contains 250 mg cycloserine.

3. List of excipients

Contains methyl paraben, propyl paraben, sunset yellow FCF, tartrazine and ponceau 4R

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Hard gelatin capsules

1 x 10's

10 x 10's

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 out of the 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.

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

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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway,
Santacruz (East), Mumbai 400055,
India
Tel: 91-22-66402323
Fax:91-22-266408128

12. WHO Reference Number (Prequalification Programme)

TB385

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

{Medicinal product subject to medical prescription.}

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blister

1. Name of the medicinal product

[TB385 trade name] Cycloserine 250 mg Capsules
Cycloserine

2. Name of the supplier

Lupin Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch>{number}

5. Other