

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB306 trade name]*

Cycloserine 250 mg capsules

2. Statement of active substance

Each hard gelatin capsule contains 250 mg cycloserine.

3. List of excipients

Contains FD&C Yellow #6/ Sunset yellow FCF

4. Pharmaceutical form and contents

40 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. Avoid excursions above 30°C. Protect from light and moisture.

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

Strides Pharma Science Limited
Strides House, Opp.IIMB,
Bilekahali, Bannerghatta Road,

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

Bengaluru, Karnataka – 560076
India
Tel. : + 91-80-67840738/290
Email: info@strides.com

12. WHO Reference Number (Prequalification Programme)

TB306

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

Medicinal product subject to medical prescription.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB306 trade name][†]

Cycloserine 250 mg capsules

2. Statement of active substance

Each hard gelatin capsule contains 250 mg cycloserine.

3. List of excipients

Contains FD&C Yellow #6/ Sunset yellow FCF

4. Pharmaceutical form and contents

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.

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

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 25°C. Avoid excursions above 30°C. Protect from light and moisture.

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

Strides Pharma Science Limited
Strides House, Opp.IIMB
Bilekahali, Bannerghatta Road
Bengaluru, Karnataka – 560076
India
Tel. : +91 -80-67840738/290
Email: info@strides.com

12. WHO Reference Number (Prequalification Programme)

TB306

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. 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

[TB306 trade name]

Cycloserine 250 mg capsules

2. Name of the supplier

Strides Pharma Science Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other