

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for blister pack

1. Name of the medicinal product

[TB416 trade name]* Cycloserine 250mg capsule

Cycloserine

2. Statement of active substance

Each capsule contains 250mg cycloserine

3. List of excipients

The capsule contains FD&C yellow #6/Sunset yellow FCF

See the patient information leaflet for further information

4. Pharmaceutical form and contents

Capsule

10x10 capsule blisters

40 capsules in HDPE bottle

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 moisture and light.

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

Strides Pharma Science Limited
Strides House, Opp. IIMB
Bannerghatta Road
Bengaluru - 560 076,
India

12. WHO Reference Number (Prequalification Programme)

TB416

13. Manufacturer's batch number

Batch {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

HDPE Bottle

1. Name of the medicinal product

[TB416 trade name][†] Cycloserine 250mg capsule

Cycloserine

2. Statement of active substance

Each capsule contains 250mg cycloserine

3. List of excipients

The capsule contains FD&C yellow #6/Sunset yellow FCF

See the patient information leaflet for further information

4. Pharmaceutical form and contents

Capsule

10x10 capsule blisters

40 capsules in HDPE bottle

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 moisture and light.

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.

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Strides House, Opp. IIMB
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12. WHO Reference Number (Prequalification Programme)

TB416

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

[TB416 trade name] cycloserine 250mg capsules
cycloserine

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