## **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

See patient information leaflet for further information.

#### 4. Pharmaceutical form and contents

Hard gelatin capsules

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

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

#### **12.** WHO Reference Number (Prequalification Programme)

TB330

#### 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 OR STRIP

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>{number}

#### 5. Other