## **LABELLING**

# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING HDPE Bottle

### 1. Name of the medicinal product

[TB222 trade name]\* Cycloserine 250 mg Capsules

#### 2. Statement of active substance

Each tablet contains 250 mg cycloserine

### 3. List of excipients

Each tablet contains Ponceau 4R (Cochineal red A). See patient information leaflet for further information.

#### 4. Pharmaceutical form and contents

Capsules

21 capsules

100 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. Store in a dry place. Keep the bottle tightly closed to protect from moisture. Protect from light.

Discard the product 50 days after initial opening.

# 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

Biocom JSC

54 Chapaevsky Cr, 355016 Stavropol

Russian Federation

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

**TB222** 

### 13. Manufacturer's batch number

<Batch> <Lot> {number}

## 14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

<sup>\*</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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## 15. Instructions on use