

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle

1. NAME OF THE MEDICINAL PRODUCT

Cycloserine 250mg Capsules *

2. STATEMENT OF ACTIVE SUBSTANCE

Each hard gelatin capsule contains 250 mg of cycloserine.

3. LIST OF EXCIPIENTS

Contains ponceau 4R (cochineal red A). See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

100 capsules
21 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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C, 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
TEL : +78652365356

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

TB222

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE