LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[TB389 trade name]* Linezolid 150 mg dispersible tablets

Linezolid

2. Statement of active substance

Each dispersible tablet contains 150 mg of linezolid

3. List of excipients

Each dispersible tablet contains 0.23mg (0.01mmol) of sodium.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

10 x 10 tablets

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 30°C. Avoid excursions above 30°C.

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

Micro Labs Limited
31, Race Course Road,

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

Bangalore - 560001, Karnataka, India.
Tel: +91-80-2237 0451 to 2237 0457
Fax : +91-80-2237 0463

12. WHO Reference Number (Prequalification Programme)

TB389

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 STRIPS

ALU/ALU Strip

1. Name of the medicinal product

[TB389 trade name] Linezolid 150 mg dispersible tablets

Linezolid

2. Name of the supplier

Micro Labs Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> {number}

5. Other