

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[TB409 trade name]* Linezolid 150 mg dispersible tablets
Linezolid

2. Statement of active substance

Each dispersible tablet contains 150 mg linezolid.

3. List of excipients

Contains mannitol and aspartame

4. Pharmaceutical form and contents

Dispersible tablet

10 x 15 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. Protect from moisture.

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

Lupin Limited

Kalpataru Inspire, 3rd Floor

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

Off Western Express Highway
Santacruz (East), Mumbai – 400055
India

12. WHO Reference Number (Prequalification Programme)

TB409

13. Manufacturer's batch number

<Batch> <Lot> {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

Aluminium strip or PVC/PVDC/Alu blister

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Linezolid

2. Name of the supplier

Lupin Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other