

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB350 trade name]*

Linezolid 600 mg film-coated tablets

2. Statement of active substance

Each film-coated tablet contains 600 mg linezolid

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Film-coated tablets

10 x10 film-coated 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. Store in the original pack

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

Off Western Express Highway

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

Santacruz (East), Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)

TB350

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

To be decided by the national medicines regulatory authority in accordance with national legislation.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister pack (PVC/PVDC-Alu or PVC-Alu)

1. Name of the medicinal product

[TB350 trade name]

Linezolid 600 mg film-coated tablets

2. Name of the supplier

Lupin limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other