

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB321 trade name]* Linezolid 600 mg Tablets

2. Statement of active substance

Each tablet contains 600 mg linezolid.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

2 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.

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

Cipla Ltd.

Cipla House

Peninsula Business Park

Ganpatrao Kadam Marg, Lower Parel

Mumbai: 400013, India

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

12. WHO Reference Number (Prequalification Programme)

TB321

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

PVC-Aluminium blister pack

1. Name of the medicinal product

[TB321 trade name] Linezolid 600 mg Tablets

2. Name of the supplier

Cipla Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB321 trade name][†] Linezolid 600 mg Tablets

Linezolid

2. Statement of active substance

Each tablet contains 600 mg linezolid

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

20 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.

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

Cipla Ltd.

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15. Instructions on use