

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister Carton

1. Name of the medicinal product

[TB297 trade name]* linezolid 600 mg film-coated tablets

Linezolid

2. Statement of active substance

Each film-coated tablet contains 600 mg linezolid

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

10 x 7 tablets

10 x 10 tablets

5 x 21 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

Store below 30°C in a dry place protected from light. Store the tablets in the blisters in the provided carton.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

11. Name and address of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

TB297

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Strip Carton

1. Name of the medicinal product

[TB297 trade name] linezolid 600 mg film-coated tablets

Linezolid

2. Statement of active substance

Each film-coated tablet contains 600 mg linezolid

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

5 x 4 tablets

2 x 10 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

Store below 30°C in a dry place protected from light. Store the tablets in the blisters in the provided carton.

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

Macleods Pharmaceuticals Limited

304, Atlanta Arcade

Marol Church Road, Andheri (East)

Mumbai – 400 059

India

12. WHO Reference Number (Prequalification Programme)

TB297

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

ALU/ALU Strip or ALU/PVC Blister

1. Name of the medicinal product

[TB297 trade name] linezolid 600mg film-coated tablets

Linezolid

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other