

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB326 trade name]* Levofloxacin 100 mg Dispersible Tablets
Levofloxacin

2. Statement of active substance

Each dispersible tablet contains levofloxacin (as hemihydrate) equivalent to levofloxacin 100 mg

3. List of excipients

Each tablet contains 20 mg of aspartame and 5.8 mg (0.2 mmol) sodium
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets
10 x 10 dispersible 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 dry place protected from light.
Store tablets in the blisters or strips 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

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

304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB326

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 Blister or Strip

1. Name of the medicinal product

[TB326 trade name] Levofloxacin 100 mg Dispersible Tablets

Levofloxacin

2. Name of the supplier

Macleods Pharmaceuticals Ltd

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other