LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB277 trade name]* Levofloxacin (as hemihydrate) 250 mg tablets

Levofloxacin (as hemihydrate)

2. Statement of active substance

Each film-coated tablet contains 250 mg of levofloxacin (as hemihydrate).

3. List of excipients

4. Pharmaceutical form and contents

5 × 20 film-coated tablets

9 × 10 film-coated tablets

10 × 10 film-coated tablets

5. Method and route of administration

Oral use.

Do not chew.

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 in the provided carton.

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

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* 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)

TB277

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

1.   **Name of the medicinal product**

   [TB277 trade name] Levofloxacin (as hemihydrate) 250 mg tablets

   Levofloxacin (as hemihydrate)

2.   **Name of the supplier**

   Macleods Pharmaceuticals Ltd

3.   **Expiry date**

   EXP {MM/YYYY}

4.   **Manufacturer's batch number**

   <Batch> <Lot>{number}

5.   **Other**