

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton Label

1. Name of the medicinal product

[TB278 trade name]* Levofloxacin (as hemihydrate) 500 mg tablets
Levofloxacin (as hemihydrate)

2. Statement of active substance

Each film-coated tablet contains 500 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}

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

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

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)

TB278

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

[TB278 trade name] Levofloxacin (as hemihydrate) 500 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