

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB227 trade name]* Levofloxacin (as hemihydrate) 500 mg tablets
Levofloxacin hemihydrate

2. Statement of active substance

Each film-coated tablet contains 500 mg levofloxacin hemihydrate

3. List of excipients

Each film-coated tablet contains FD&C Yellow#5 (tartrazine).
See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets
1 x 10 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

Do not store above 30°C. Keep away from light and moisture.

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

Cipla Ltd.,
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg,
Lower Parel
Mumbai - 400 013
India

12. WHO Reference Number (Prequalification Programme)

TB227

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

Bottle label

1. Name of the medicinal product

[TB227 trade name][†] Levofloxacin (as hemihydrate) 500 mg tablets
Levofloxacin hemihydrate

2. Statement of active substance

Each film-coated tablet contains 500 mg levofloxacin hemihydrate

3. List of excipients

Each film-coated tablet contains FD&C Yellow#5 (tartrazine).
See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets
50 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

Do not store above 30°C. Keep away from light and moisture.

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

Cipla Ltd.,
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg,
Lower Parel
Mumbai - 400 013
India

12. WHO Reference Number (Prequalification Programme)

TB227

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

Blister

1. Name of the medicinal product

[TB227 trade name] Levofloxacin (as hemihydrate) 500 mg tablets
Levofloxacin hemihydrate

2. Name of the supplier

Cipla Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other