

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle label

1. Name of the medicinal product

[TB205 trade name]*

Levofloxacin 250 mg film-coated tablets

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

50 film-coated 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

Do not store above 30oC. 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

11. Name and address of the supplier

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

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

India
Tel. No.: 9122 28426000
Fax No.: 9122 24826120
Email: globalra@cipla.com

12. WHO Reference Number (Prequalification Programme)

TB205

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

To be decided by the national medicines regulatory authority in accordance with national legislation.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister label

1. Name of the medicinal product

[TB205 trade name][†]

Levofloxacin 250 mg film-coated tablets

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

10 film-coated 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

Do not store above 30oC. 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

11. Name and address of the supplier

Cipla Ltd.,
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Peninsula Business Park
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12. WHO Reference Number (Prequalification Programme)

TB205

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<Batch> <Lot> {number}

14. General classification for supply

To be decided by the national medicines regulatory authority in accordance with national legislation.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister label

1. Name of the medicinal product

[TB205 trade name]

Levofloxacin 250 mg film-coated tablets

2. Name of the supplier

Cipla Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other