

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB373 trade name]* Levofloxacin 500 mg tablets
Levofloxacin (as hemihydrate)

2. Statement of active substance

Each tablet contains 500 mg levofloxacin

3. List of excipients

Contains colour FD&C red #40 (Allura red).
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets.
3 x 6 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 {DD/MMM/YY}

9. Special storage conditions

Store below 30°C. Protect 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

PT Sanbe Farma
Jl. Taman Sari No. 10
Bandung 40116, Indonesia

12. WHO Reference Number (Prequalification Programme)

TB373

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

Aluminium strips

1. Name of the medicinal product

[TB373 trade name] Levofloxacin 500 mg tablets

Levofloxacin (as hemihydrate)

2. Name of the supplier

PT Sanbe Farma

3. Expiry date

EXP {DD/MMM/YY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other