

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

- 1. Name of the medicinal product**
[TB373 trade name]* Levofloxacin (as hemihydrate) 500 mg tablets
- 2. Statement of active substance**
Each tablet contains 500 mg levofloxacin (as hemihydrate)
- 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**
- 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.

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

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Aluminium strips

1. Name of the medicinal product

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

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