

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

- 1. Name of the medicinal product**
[TB373 trade name]* Levofloxacin 500 mg tablets
Levofloxacin
- 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 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**