

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB378 trade name]* Levofloxacin (as hemihydrate) 500 mg tablets
Levofloxacin (as hemihydrate)

2. Statement of active substance

Each film-coated tablet contains 500 mg of levofloxacin (as hemihydrate)

3. List of excipients

Each tablet contains about 0.01 mg FD&C yellow #5 /tartrazine aluminium lake, 0.09 mg FD&C yellow #6/sunset yellow FCF aluminium lake and 0.77 mg Lecithin (soya).

4. Pharmaceutical form and contents

Film-coated tablets
1 × 4 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

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

Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd
333 Jiangnan Road
Hengdian, Dongyang
Zhejiang province
P.R. China

12. WHO Reference Number (Prequalification Programme)

TB378

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

PVC-Aluminium blister

1. Name of the medicinal product

[TB378 trade name] Levofloxacin (as hemihydrate) 500 mg tablets

Levofloxacin (as hemihydrate)

2. Name of the supplier

Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other