

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB377 trade name]* Levofloxacin (as hemihydrate) 250mg tablets
Levofloxacin

2. Statement of active substance

Each tablet contains 250 mg of levofloxacin (as hemihydrate).

3. List of excipients

Each tablet contains about 0.41mg of FD&C yellow #5 /tartrazine aluminium lake and 0.38 mg of lecithin (soya)

4. Pharmaceutical form and contents

Film-coated tablets
10 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

Do not store above 30 °C. Preserve in tight containers.

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)

TB377

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

[TB377 trade name] Levofloxacin (as hemihydrate) 250mg tablets

Levofloxacin

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