

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB354 trade name]* Levofloxacin 500 mg tablets

Levofloxacin

2. Statement of active substance

Each film-coated tablet contains levofloxacin hemihydrate 512.45 mg equivalent to levofloxacin 500 mg

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet

10 x 10 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 {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Protect from light.

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. Dankos Farma
Jalan Rawa Gatel Blok III S
Kavling 35-40, Kawasan industri
Pulogadung, Kel Jatinegara, Kec. Cakung
Jakarta Timur 13930

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

Indonesia

12. WHO Reference Number (Prequalification Programme)

TB354

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 STRIP

Aluminium foil

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Levofloxacin

2. Name of the supplier

PT. Dankos Farma

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other