

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton-Aluminium strip

1. Name of the medicinal product

[TB354 trade name]*

Levofloxacin (as hemihydrate) 500 mg film-coated tablets

2. Statement of active substance

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

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

3 x 10 tablets

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

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

Pulogadung, Kel Jatinegara, Kec. Cakung
Jakarta Timur 13930
Indonesia

12. WHO Reference Number (Prequalification Programme)

TB354

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

To be decided by the national medicines regulatory authority in accordance with national legislation.

15. Instructions on use