LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARTON (Alu/Alu Blister Pack)

1. Name of the medicinal product

[TB 342 trade name][*] Moxifloxacin (as hydrochloride) 100 mg dispersible tablets

Moxifloxacin (as hydrochloride)

2. Statement of active substance

Each dispersible tablet contains moxifloxacin hydrochloride equivalent to 100 mg moxifloxacin.

3. List of excipients

Contains aspartame.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

10 × 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

Store below 30°C, in a dry place, protected from light.

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

Macleods Pharmaceuticals Limited

304, Atlanta Arcade

Marol Church Road

Andheri (East)

400 059 Mumbai

India

12. WHO Reference Number (Prequalification Programme)

TB342

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
Alu/Alu blister pack

1. Name of the medicinal product

[TB342 trade name] Moxifloxacin (as hydrochloride) 100 mg dispersible tablets

Moxifloxacin (as hydrochloride)

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other