LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label (PVC/PE/PVdC-Alu foil blister)

1. Name of the medicinal product

[TB349 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

4. Pharmaceutical form and contents

Dispersible tablets

10 x 10 tablets

14 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. Avoid excursions above 30°C. Protect from light and moisture.

Store tablets in blisters in the provided carton.

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

Micro Labs Limited
(Unit – 03)
92, Sipcot Industrial Complex

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

Hosur – 635126
Tamil Nadu
India

12. WHO Reference Number (Prequalification Programme)

TB349

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label (Alu-Alu strip)

1. Name of the medicinal product

[TB349 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

4. Pharmaceutical form and contents

Dispersible 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. Avoid excursions above 30°C. Protect from light and moisture.

Store tablets in strips in the provided carton.

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

Micro Labs Limited
(Unit – 03)
92, Sipcot Industrial Complex
Hosur – 635126
Tamil Nadu

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

India

12. WHO Reference Number (Prequalification Programme)

TB349

13. Manufacturer's batch number

<Batch> {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/PE/PVdC-Alu blister or Alu-Alu strip

1. Name of the medicinal product

[TB349 trade name] Moxifloxacin (as hydrochloride)100 mg dispersible tablets

Moxifloxacin (as hydrochloride)

2. Name of the supplier

Micro Labs Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> {number}

5. Other