LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[TB263 trade name]* Moxifloxacin (hydrochloride) 400 mg film-coated tablets

Moxifloxacin (hydrochloride)

2. Statement of active substance

Each film coated tablet contains moxifloxacin hydrochloride equivalent to 400 mg moxifloxacin

3. List of excipients

Each tablet contains lactose monohydrate.

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets
30 tablets
100 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. Store in the original container. Protect 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

Micro Labs Limited
31, Race Course Road
Bengaluru– 560001
Karnataka
India

12. WHO Reference Number (Prequalification Programme)

TB263

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB263 trade name][†] Moxifloxacin (hydrochloride) 400 mg film-coated tablets

Moxifloxacin (hydrochloride)

2. Statement of active substance

Each film coated tablet contains moxifloxacin hydrochloride equivalent to 400 mg moxifloxacin

3. List of excipients

Each tablet contains lactose monohydrate.

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets

10 x 10 film-coated 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. Store in the original container. Protect 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

Micro Labs Limited
31, Race Course Road
Bengaluru– 560001
Karnataka
India

12. WHO Reference Number (Prequalification Programme)

TB263

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

Blisters (PVC/PE/PVdC-Al and cold formable Al–Al blisters)

1. Name of the medicinal product

[TB263 trade name] Moxifloxacin (hydrochloride) 400 mg film-coated tablets

Moxifloxacin (hydrochloride)

2. Name of the supplier

Micro Labs Limited.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other