

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Cartoon

1. Name of the medicinal product

[TB376 trade name]* Moxifloxacin (as hydrochloride) 400 mg tablets
Moxifloxacin (hydrochloride)

2. Statement of active substance

Each tablet contains moxifloxacin hydrochloride equivalent to 400 mg moxifloxacin.

3. List of excipients

Each tablet contains lactose monohydrate.
See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablet
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

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

Lupin Limited

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

Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East), Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)

TB376

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

PVC/PVdC-Alu and PVC-Alu blister cards

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Moxifloxacin (as hydrochloride)

2. Name of the supplier

Lupin Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other