

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB253 trade name]*

Moxifloxacin 400 mg film-coated tablets

2. Statement of active substance

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

3. List of excipients

Contains lactose

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

5x1 film-coated tablets

10x1 film-coated tablets

10x10 film-coated 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 out of the sight and reach of children.

7. Other special warning(s), if necessary

Not applicable

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C, protect from light and moisture. Store tablets in blisters in the provided carton.

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

¹ Formerly Ranbaxy Laboratories Ltd

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

NA

11. Name and address of the supplier

Sun Pharmaceutical Industries
Limited, Sun House, 201 B/1,
Western Express
Highway, Goregaon
(East),
Mumbai - 400063, India
Tel.: +91-124-4194400, Ext 4138

12. WHO Reference Number (Prequalification Programme)

TB253

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 THE IMMEDIATE PACKAGING

Blister

1. Name of the medicinal product

[TB253 trade name]

Moxifloxacin 400 mg film-coated tablets

2. Name of the supplier

Sun Pharmaceutical Industries Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other