

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB230 trade name]*

Moxifloxacin 400 mg film-coated tablets

2. Statement of active substance

Each 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

1 x 5 film-coated tablets

20 x 5 film-coated tablets

10 x 7 film-coated tablets

10 x 10 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

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

Keep 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. Protect from light. Store in the original container

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

Macleods Pharmaceuticals Limited
Atlanta Arcade, 3rd Floor, Church Road, near Leela Hotel,
Andheri-Kurla Road
Andheri (East)
400 059 Mumbai
India
Phone: +91-22-66762800
Fax: +91-22-2821 6599
E-mail: vijay@macleodsPharma.com
sjadhav@macleodspharma.com

12. WHO Reference Number (Prequalification Programme)

TB230

13. Manufacturer's batch number

<BN> {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

1. Name of the medicinal product

[TB230 trade name]†

Moxifloxacin 400 mg film-coated tablets

2. Name of the supplier

Macleods Pharmaceuticals Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

BN {number}

5. Other

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