

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB311 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

Each film-coated tablet contains lactose monohydrate.
See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets
1 x 5 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 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

Store at or below 30°C. Protect from light and moisture

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

Getz Pharma (Pvt) Limited
29-30/27, Korangi Industrial Area
Karachi-74900
Pakistan

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

12. WHO Reference Number (Prequalification Programme)

TB311

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

For Oral use.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Alu-Alu blister

1. Name of the medicinal product

[TB311 trade name]
Moxifloxacin 400 mg film-coated tablets

2. Name of the supplier

Getz Pharma (Pvt) Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

Batch {number}

5. Other