LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB315 trade name][*]

2. Statement of active substance

Each film coated tablet contains:

Moxifloxacin Hydrochloride Ph. Eur. 436.33 mg, equivalent to Moxifloxacin 400 mg

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

10 x 1 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. Store in the original package in order to protect from light.

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

Hetero Labs Limited
Hetero Corporate, 7-2-A2
Industrial Estates

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

Sanath Nagar, Hyderabad
Telangana, 500 018
India.

12. WHO Reference Number (Prequalification Programme)

TB315

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

1. Name of the medicinal product

[TB315 trade name] Moxifloxacin (as hydrochloride) 400 mg Tablets

2. Name of the supplier

Hetero Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<BN>/ LOT No.