

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

Oflox 400 Tablets *

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 400 mg of ofloxacin.

3. LIST OF EXCIPIENTS

Contains lactose. See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

100 film-coated tablets
500 film-coated tablets
1000 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

8. EXPIRY DATE

EXP {MM/YYYY}

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

Cipla Ltd.
Mumbai Central
Mumbai- 400008
India
Tel : + 91 22 23082891 / 23095521

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

TB225

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

14. (Advice on) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

PVC-Al blister

1. NAME OF THE MEDICINAL PRODUCT

Oflox 400 Tablets

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 400 mg of ofloxacin.

3. LIST OF EXCIPIENTS

Contains lactose. See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

100 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

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

Cipla Ltd.
Mumbai Central
Mumbai- 400008
India
TEL :+ 91 22 25716031 / 25716015

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

TB225

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <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 STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Oflox 400 Tablets

2. NAME OF THE SUPPLIER

Cipla Ltd

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}