

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

HDPE Bottle

1. NAME OF THE MEDICINAL PRODUCT

Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets¹

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains atazanavir sulfate equivalent to 300 mg atazanavir and 100 mg ritonavir

3. LIST OF EXCIPIENTS

Contains lactose. See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHO PAR the proprietary name is given as an example only.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. 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

Cipla Ltd.
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA632

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Carton label

1. NAME OF THE MEDICINAL PRODUCT

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3. LIST OF EXCIPIENTS

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4. PHARMACEUTICAL FORM AND CONTENTS

30 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. Store tablets in blisters in the provided carton.

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.
Cipla House

Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

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13. MANUFACTURER'S BATCH NUMBER

<BN> {number}

14. 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

Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets

2. NAME OF THE SUPPLIER

Cipla Ltd.

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

BN {number}