LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton label

1. NAME OF THE MEDICINAL PRODUCT

Lopinavir/Ritonavir tablets 200 mg/50 mg *.

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 200 mg lopinavir and 50 mg ritonavir.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

120 tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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 reach and sight 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 DRA responsibility. Throughout this WHOPAR 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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500034,
Telangana,
India
Tel No: +91 40 39258109
Email: intiyaz.basade@mylan.in

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA411

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 IMMEDIATE PACKAGING

Bottle label

1. NAME OF THE MEDICINAL PRODUCT

Lopinavir/Ritonavir tablets 200 mg/50 mg

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 200 mg lopinavir and 50 mg ritonavir.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

120 tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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 reach and sight 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 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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500034,
Telangana,
India
Tel No: +91 40 39258109
Email: imtiyaz.basade@mylan.in

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA411

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

Blisters carton label

1. NAME OF THE MEDICINAL PRODUCT

Lopinavir/Ritonavir tablets 200 mg/50 mg†.

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 200 mg lopinavir and 50 mg ritonavir.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

10 x 12 tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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 reach and sight 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 DRA responsibility. Throughout this WHOPAR 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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500034,
Telangana,
India
Tel No: +91 40 39258109
Email: imtiyaz.basade@mylan.in

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA411

13. MANUFACTURER’S BATCH NUMBER

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

14. 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**
   Lopinavir/Ritonavir tablets 200 mg/50 mg

2. **NAME OF THE SUPPLIER**
   Mylan Laboratories Limited

3. **EXPIRY DATE**
   EXP {MM/YYYY}

4. **BATCH NUMBER**
   <Batch> <Lot> <BN> {number}