

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. NAME OF THE MEDICINAL PRODUCT

Ritonavir Tablets 100 mg

2. STATEMENT OF ACTIVE SUBSTANCE

Each film coated tablet contains 100 mg ritonavir.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

30 tablets and 120 tablets

10x1 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.

Ritonavir Tablets 100 mg
(Mylan Laboratories. Ltd), HA467

WHOPAR part 5

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)

HA467

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

Ritonavir Tablets 100 mg

2. STATEMENT OF ACTIVE SUBSTANCE

Each film coated tablet contains 100 mg ritonavir

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

30 tablets and 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.

Ritonavir Tablets 100 mg
(Mylan Laboratories. Ltd), HA467

WHOPAR part 5

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

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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

Ritonavir Tablets 100 mg
(Mylan Laboratories. Ltd), HA467

WHOPAR part 5

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Alu-Alu cold form blister

- 1. Name of the medicinal product**
[HA467 trade name] Ritonavir Tablets 100 mg
- 2. Name of the supplier**
Mylan Laboratories Limited
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Manufacturer's batch number**
<Batch> <Lot>{number}
- 5. Other**