

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton box/HDPE bottle**

**1. NAME OF THE MEDICINAL PRODUCT**

Ritonavir 25 mg Tablets \*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each film coated tablet contains 25 mg ritonavir.

**3. LIST OF EXCIPIENTS**

Contains sodium. 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 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}

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

Ritonavir 25 mg Tablets  
(Mylan Laboratories Ltd), HA621

WHOPAR part 5

## **9. SPECIAL STORAGE CONDITIONS**

Do not store above 30<sup>0</sup>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](mailto:imtiyaz.basade@mylan.in)

## **12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

HA621

## **13. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

## **14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

## **15. INSTRUCTIONS ON USE**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

**HDPE Bottle label**

**1. NAME OF THE MEDICINAL PRODUCT**

Ritonavir 25 mg Tablets<sup>†</sup>

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each film coated tablet contains 25 mg ritonavir

**3. LIST OF EXCIPIENTS**

Contains sodium. 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 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}

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the product name is given as an example only.

Ritonavir 25 mg Tablets  
(Mylan Laboratories Ltd), HA621

WHOPAR part 5

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 30<sup>0</sup>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**

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**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

HA621

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

**14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**