

## **LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGING

### Carton

**1. Name of the medicinal product**

[HA467 trade name]\*

Ritonavir 100 mg film-coated tablet

**2. Statement of active substance**

Each film-coated tablet contains 100 mg ritonavir.

**3. List of excipients**

Each tablet contains 87.76 mg of sodium.

See the patient information leaflet for further information.

**4. Pharmaceutical form and contents**

30 tablets

120 tablets

1x10 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 this medicine 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 in original container.

**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

\*\* Previously known as Matrix Laboratories Limited.

**11. Name and address of the supplier**

Mylan Laboratories Limited  
Plot No. 564/A/22, Road No.92, Jubilee Hills  
Hyderabad - 500096, Telangana,  
India

**12. WHO Reference Number (Prequalification Programme)**

HA467

**13. Manufacturer's batch number**

<Batch> <Lot> {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**

HDPE bottle

### **1. Name of the medicinal product**

[HA467 trade name]

Ritonavir 100 mg film-coated tablet

### **2. Statement of active substance**

Each film-coated tablet contains 100 mg ritonavir.

### **3. List of excipients**

Each tablet contains 87.76 mg of sodium.

See the patient information leaflet for further information.

### **4. Pharmaceutical form and contents**

30 tablets

120 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 this medicine 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 in 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 - 500096, Telangana,  
India

**12. WHO Reference Number (Prequalification Programme)**

HA467

**13. Manufacturer's batch number**

<Batch> <Lot> {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 STRIP**

**Blister**

**1. Name of the medicinal product**

[HA467 trade name]

Ritonavir 100 mg film-coated tablet

**2. Name of the supplier**

Mylan Laboratories Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**