

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Carton

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

[HA679 trade name]\*

Lopinavir/ritonavir 40 mg/10 mg granules for oral suspension

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

Each sachet contains 40 mg lopinavir and 10 mg ritonavir.

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

Contains mannitol

See patient information leaflet for further information.

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

Granules for oral suspension

120 sachets

### **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 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**

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

**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)**

HA697

**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 SACHETS**

Sachet

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

[HA697 trade name]

Lopinavir/ritonavir 40 mg/10 mg granules for oral suspension

### **2. Name of the supplier**

Mylan Laboratories Limited

### **3. Expiry date**

EXP {MM/YYYY}

### **4. Manufacturer's batch number**

<Batch> <Lot>{number}

### **5. Other**