

## **LABELLING**

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

Carton label

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

[HA574 trade name]\*Lopinavir/ritonavir 200mg/50 mg tablets

Lopinavir and ritonavir

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

Each tablet contains 200 mg lopinavir and 50 mg ritonavir.

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

See patient information leaflet for further information.

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

60 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 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**

Store below 30°C, in dry place protected from light.

### **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**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059, India  
Tel: +91-22-66762800  
Fax:+91 -22-29256599

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

HA574

**13. Manufacturer's batch number**

<Batch>{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 label

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

[HA574 trade name]<sup>†</sup>Lopinavir/ritonavir 200mg/50 mg tablets

Lopinavir and ritonavir

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

Each tablet contains 200 mg lopinavir and 50 mg ritonavir.

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

See patient information leaflet for further information.

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

60 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 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**

Store below 30°C, in dry place protected from light.

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

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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

HA574

**13. Manufacturer's batch number**

<Batch>{number}

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**15. Instructions on use**