

## **LABELLING**

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

Bottle label and carton

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

[HA628 trade name]<sup>1</sup> Darunavir (as ethanolate) 600 mg Tablets  
Darunavir (as ethanolate)

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

Each film-coated tablet contains 600 mg Darunavir

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

Contains FD&C yellow #6/Sunset yellow FCF Aluminium Lake

See patient information leaflet for further information

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

Film-coated tablets

1 x 60 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 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.

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<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**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**

Cipla Ltd.  
Cipla House  
Peninsula Business Park  
Ganpatrao Kadam Marg  
Lower Parel Mumbai: 400013  
India.

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

HA628

**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**