

## **LABELLING**

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

Outer carton

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

[HP022 trade name]\* Daclatasvir (as dihydrochloride) 60 mg tablets

Daclatasvir (as dihydrochloride)

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

Each film-coated tablet contains 60 mg of daclatasvir (as dihydrochloride)

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

Each film-coated tablet contains about 115.58 mg of lactose monohydrate

See patient information leaflet for further information

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

Film coated tablets

HDPE bottle: 28 tablets

Blister pack: 2 x14 tablets

### **5. Method and route of administration**

Oral use.

Do not chew.

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.

### **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**

Cipla Limited  
Cipla House, Peninsula Business Park  
Ganpatrao Kadam Marg  
Lower Parel  
Mumbai 400 013  
India

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

HP022

**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 OUTER PACKAGING**

HDPE bottle label

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

[HP022 trade name]<sup>†</sup>

Daclatasvir dihydrochloride 60 mg tablets

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

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EXP {MM/YYYY}

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

Medicinal product subject to medical prescription.

**15. Instructions on use**

## **MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

Blister

**1. Name of the medicinal product**

[HP022 trade name]

Daclatasvir dihydrochloride 60 mg tablets

**2. Name of the supplier**

Cipla Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**