

## **LABELLING**

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

HDPE Bottle

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

[HP034 trade name]\* Daclatasvir (dihydrochloride) 60mg tablets

Daclatasvir (dihydrochloride)

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

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

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

The tablets contain lactose monohydrate.

See the patient information leaflet for further information

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

Film-coated Tablets

28 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 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**

Zydus Lifesciences Limited  
“Zydus Corporate Park”,  
Scheme no. 63, survey no. 536,  
Khoraj (Gandhinagar), Near. Vaishnodevi circle,  
Ahmedabad, Gujarat  
India – 382441  
E-mail: Drugsafety@zyduslife.com

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

HP034

**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 OUTER PACKAGING**

Blister carton

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

[HP034 trade name]<sup>†</sup> Daclatasvir (dihydrochloride) 60mg tablets

Daclatasvir (dihydrochloride)

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

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

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

The tablets contain lactose monohydrate.

See the patient information leaflet for further information

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

Film-coated Tablets

3 x 10 film coated tablets

10 x 10 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**

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

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

Zydus Lifesciences Limited  
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E-mail: Drugsafety@zyduslife.com

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

HP034

**13. Manufacturer’s batch number**

<Batch> {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**

Blisters (Alu/Alu foil strip packs)

**1. Name of the medicinal product**

[HP034 trade name] Daclatasvir (dihydrochloride) 60mg tablets

Daclatasvir (dihydrochloride)

**2. Name of the supplier**

Zydus Lifesciences Limited. India

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> {number}

**5. Other**