

## **LABELLING**

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

HDPE bottle

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

[HP028 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**

The tablets contain lactose anhydrous.  
See the patient information leaflet for further information.

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

Film-coated tablets

28 tablets

500 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}  
500's Count: Discard the product 30 days after initial opening.

### **9. Special storage conditions**

Do not store above 30°C. Store in the original container. Do not remove silica gel canister from the bottle.

### **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**

Laurus Labs Limited  
2<sup>nd</sup> Floor, Serene Chambers, Road No.7  
Banjara hills, Hyderabad  
Telangana – 500034  
India

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

[HP028 trade name]

**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**