

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HP027 trade name]* Daclatasvir (as dihydrochloride) 30 mg Tablets

2. Statement of active substance

Each film-coated tablet contains 30 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

11. Name and address of the supplier

Laurus Labs Limited

2nd Floor, Serene Chambers, Road No.7

Banjara hills, Hyderabad

Telangana – 500034

India

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

12. WHO Reference Number (Prequalification Programme)

[HP027 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