

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HP012 trade name]* 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

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}

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

9. Special storage conditions

Do not store above 30°C. Protect from moisture. Protect from light.

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

Hetero Labs Ltd
Hetero Corporate,
7-2-A2, Industrial Estates
Sanath Nagar, Hyderabad
Telangana, 500 018
India

12. WHO Reference Number (Prequalification Programme)

HP012

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

Blister Carton

1. Name of the medicinal product

[HP012 trade name][†] 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

10 x 10 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. Protect from moisture. Protect from light.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) 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

Hetero Labs Ltd
Hetero Corporate,
7-2-A2, Industrial Estates
Sanath Nagar, Hyderabad
Telangana, 500 018
India

12. WHO Reference Number (Prequalification Programme)

HP012

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister card

1. Name of the medicinal product

[HP012 trade name] 60 mg tablets daclatasvir (as dihydrochloride)

2. Name of the supplier

Hetero Labs Ltd
Hetero Corporate,
7-2-A2, Industrial Estates
Sanath Nagar, Hyderabad
Telangana, 500 018
India

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other