LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HP021 trade name]* Daclatasvir (as dihydrochloride) 30 mg tablets

Daclatasvir (as dihydrochloride)

2. Statement of active substance

Each film-coated tablet contains 30 mg of daclatasvir (as dihydrochloride)

3. List of excipients

Each film-coated tablet contains about 57.8 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

* 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)

HP021

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

[HP021 trade name][†]

Daclatasvir dihydrochloride 30 mg tablets

2. Statement of active substance

Each film-coated tablet contains 30 mg of daclatasvir (as dihydrochloride)

3. List of excipients

Each film-coated tablet contains about 57.8 mg of lactose monohydrate

See patient information leaflet for further information

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Film coated tablets

28 tablets

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EXP {MM/YYYY}

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13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

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15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blister

1. **Name of the medicinal product**

   [HP021 trade name]

   Daclatasvir dihydrochloride 30 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**