LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HP016 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 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}

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

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

11. Name and address of the supplier

Mylan Laboratories Limited

Plot No.564/A/22, Road No. 92, Jubilee Hills

Hyderabad – 500096

Telangana

India

Email: ProductSafety@viatris.com

12. WHO Reference Number (Prequalification Programme)

HP016

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 HDPE BOTTLE

HDPE bottle

1. Name of the medicinal product

[HP016 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 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}

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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