

## **LABELLING**

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

### **Carton for blister pack**

**1. Name of the medicinal product**

[HA678 trade name]\*

Dolutegravir (as sodium) 50 mg tablets

**2. Statement of active substance**

Each film-coated tablet contains 50 mg dolutegravir (as sodium).

**3. List of excipients**

See patient information leaflet for further information.

**4. Pharmaceutical form and contents**

Film-coated tablets

1 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 out of the reach and sight 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**

**11. Name and address of the supplier**

Mylan Laboratories Limited

Plot No. 564/A/22

Road No. 92, Jubilee Hills

Hyderabad – 500096, Telangana

India

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

HA678

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

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

## **15. Instructions on use**

## **MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

### **PVC/Aclar blister**

- 1. Name of the medicinal product**  
[HA678 trade name]  
Dolutegravir (as sodium) 50 mg tablets
- 2. Name of the supplier**  
Mylan Laboratories Limited
- 3. Expiry date**  
EXP {MM/YYYY}
- 4. Manufacturer's batch number**  
<Batch> <Lot>{number}
- 5. Other**

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

### **Plastic (HDPE) Bottle**

**1. Name of the medicinal product**

[HA678 trade name]

Dolutegravir (as sodium) 50 mg tablets

**2. Statement of active substance**

Each film-coated tablet contains 50 mg dolutegravir (as sodium).

**3. List of excipients**

See patient information leaflet for further information.

**4. Pharmaceutical form and contents**

Film-coated tablets

30 tablets

90 tablets

180 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 and sight 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**

**11. Name and address of the supplier**

Mylan Laboratories Limited

Plot No. 564/A/22

Road No. 92, Jubilee Hills

Hyderabad – 500096, Telangana

India

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

HA678

**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**