

## **LABELLING**

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

### **HDPE bottle**

#### **1. Name of the medicinal product**

[HA746 trade name]\*

Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil fumarate 50mg/300mg/300mg tablets

#### **2. Statement of active substance**

Each film-coated tablet contains 50 mg dolutegravir (as sodium), 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate

#### **3. List of excipients**

Contains mannitol

#### **4. Pharmaceutical form and contents**

Film-coated tablets

30 tablets

90 tablets

180 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 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.

Discard 90 days after first opening. *(This is only applicable to pack sizes of 90 and 500).*

Discard 180 days after first opening. *(This is only applicable to pack size of 180).*

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

Cipla Limited  
Cipla House, Peninsula Business Park  
Ganpatrao, Kadam Marg, Lower Parel  
Mumbai, Maharashtra 400013  
India

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

HA702

**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**