

## **LABELLING**

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

### **Plastic (HDPE) bottle**

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

[HA439 trade name]\* Emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets  
Emtricitabine/tenofovir disoproxil fumarate

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

Each film-coated tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg tenofovir disoproxil or 136 mg tenofovir).

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

Each tablet contains lactose.

See the patient information leaflet for further information.

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

Film-coated tablet

30 film-coated 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.

#### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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

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

Cipla Ltd  
Cipla House, Peninsula Business Park  
Ganpatrao Kadam Marg, Lower Parel  
Mumbai, Maharashtra, 400 013  
India

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

HA439

**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**