

## **LABELLING**

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

### **HDPE Bottle label**

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

[HA732 trade name]\*

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 400 mg/300 mg/300 mg Tablets

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

Each film-coated tablet contains 400 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate.

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

Each tablet lactose monohydrate.

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 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. Avoid excursions above 30°C. Store in the original container. Keep the bottle tightly closed.

**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**

Laurus Labs Limited  
2nd Floor, Serene Chambers, Road No.7  
Banjara hills, Hyderabad, Telangana- 500034  
India

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

HA732

**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**