

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER 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

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate

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

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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**

Laurus Labs Limited  
Plot No.103, Road No.1,  
Jubilee Hills,  
Hyderabad – 500 033,  
Telangana,  
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**