

## **LABELLING**

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

HDPE bottle/Carton

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

[HA759 trade name]\* efavirenz/lamivudine/tenofovir disoproxil fumarate 400mg/300mg/300mg 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 contains lactose monohydrate.

This medicine is essentially “sodium-free”.

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.

Discard 90 days after first opening. (This is applicable only to pack size of 90 tablets)

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

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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**

Hetero Labs Limited  
Hetero Corporate  
7-2-A2, Industrial Estates  
Sanath Nagar  
Hyderabad  
Ranga Reddy District  
Telangana, 500 018  
India.

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

HA759

**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**