

## **LABELLING**

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

HDPE Bottle

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

[HA717 trade name]\* Emtricitabine/Tenofovir disoproxil fumarate 200 mg/300 mg  
Tablets

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

Each film-coated tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate.

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

Each film-coated tablet contains 145 mg of lactose anhydrous and 8.4mg of lactose monohydrate.

See patient information leaflet for further information.

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

Film-coated tablets

30 Tablets

90 Tablets

### **5. Method and route of administration**

Oral use.

Do not chew.

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. 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)**

HA717

**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**