

## **LABELLING**

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

HDPE bottle

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

[HA714 trade name]\* Efavirenz / Lamivudine / Tenofovir disoproxil fumarate  
400 mg / 300 mg /300 mg tablets

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

Each tablet contains 400 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate

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

The tablets also contain lactose.  
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. Protect from light. Avoid excursions above 30°C.

### **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**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059, India.

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

HA714

### **13. Manufacturer's batch number**

<Batch> <Lot> {number}

---

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

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**15. Instructions on use**