

## **LABELLING**

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

HDPE bottle

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

[HA444 trade name]<sup>\*</sup> Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate 600 mg/200 mg/300 mg Tablets

Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate

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

Each film-coated tablet contains 600 mg efavirenz, 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

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

Contains lactose.

See patient information leaflet for further information.

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

30 film-coated tablets

28 film-coated 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 and sight 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 package. Keep the container tightly closed.

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

<sup>#</sup> Formerly known as 'Matrix Laboratories Limited'

**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**

Mylan Laboratories Limited,  
Plot No. 564/A/22, Road No.92, Jubilee Hills  
Hyderabad - 500096, Telangana,  
India  
[Email: ProductSafety@viatris.com](mailto:ProductSafety@viatris.com)

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

HA444

**13. Manufacturer's batch number**

Batch {number}

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

Medicinal product subject to medical prescription.

**15. Instructions on use**