

## **LABELLING**

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

### **Bottle / Carton label**

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

[HA500 trade name]<sup>1</sup> Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate 600mg/200mg/300mg 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.

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

Each tablet contains small amounts of soya lecithin.

See patient information leaflet for further information.

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

30 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 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. Store in a well closed container.

#### **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**

Cipla Ltd.

---

<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Cipla House, Peninsula Business Park,  
Ganpatrao Kadam Marg, Lower Parel,  
Mumbai 400 013,  
India

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

HA500

**13. Manufacturer's batch number**

<Batch> { number }

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

Medicinal product subject to medical prescription.

**15. Instructions on use**