

## **LABELLING**

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

HDPE bottle

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

[HA552 trade name]\* Emtricitabine/tenofovir disoproxil fumarate 200mg/300mg tablets  
Emtricitabine/tenofovir disoproxil fumarate

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

Each tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate

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

Contain lactose.

See patient information leaflet for further information.

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

Film-coated tablets

30 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 25°C

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

---

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

**11. Name and address of the supplier**

Strides Pharma Science Limited  
Strides House, Bilekahalli  
Bannerghatta Road  
Bangalore – 560 076  
India  
Tel: +91-80-6784 0000  
E-mail: [corpcomm@strides.com](mailto:corpcomm@strides.com)

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

HA552

**13. Manufacturer's batch number**

<Batch> {number}

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

Medicinal product subject to medical prescription.

**15. Instructions on use**