

## **LABELLING**

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

HDPE bottle

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

[HP030 trade name]\* Tenofovir disoproxil fumarate 300 mg tablets

Tenofovir disoproxil fumarate

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

Each film-coated tablet contains 300 mg of tenofovir disoproxil fumarate equivalent to 245 mg of tenofovir disoproxil.

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

Contains lactose

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

Film-coated tablets

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 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**

Store below 30°C. Keep the bottle well-closed in order to protect from moisture. Do not remove the desiccant.

Discard the tablets 30 days after first opening

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

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

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

Shijiazhuang Lonzeal Pharmaceuticals Co., Ltd.  
No.16, West Ring Road,  
Shenze, Shijiazhuang, Hebei,  
P. R. China 052560

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

HP030

**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**