

## **LABELLING**

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

Plastic (HDPE) bottle

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

[HA666 trade name]\*

Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

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

Each tablet contains 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir.

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

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 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.

### **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 Limited

Cipla House

Peninsula Business Park

Ganpatrao Kadam Marg

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

Lower Parel  
Mumbai: 400013  
India

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

HA666

**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**

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

### **Blister Carton**

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

[HA666 trade name]<sup>†</sup>

Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

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

Each tablet contains 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir.

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

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 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.

#### **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 Limited

Cipla House

Peninsula Business Park

Ganpatrao Kadam Marg

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

Lower Parel  
Mumbai: 400013  
India

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

HA666

**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**

## **MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP**

### **Alu-Alu blisters**

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

[HA666 trade name]<sup>‡</sup>

Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

#### **2. Name of the supplier**

Cipla Ltd

#### **3. Expiry date**

EXP {MM/YYYY}

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

<Batch> <Lot>{number}

#### **5. Other**

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