

## LABELLING

### PARTICULARS TO APPEAR ON THE OUTER PACKAGING

#### Carton label

**1. Name of the medicinal product**

[HA729 trade name]\* Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets

**2. Statement of active substance**

Each film-coated tablet contains Lamivudine 300 mg Tenofovir disoproxil fumarate 300 mg (equivalent to tenofovir disoproxil 245 mg or tenofovir 136 mg)

**3. List of excipients**

Contains 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 out of the reach of children.

**7. Other special warning(s), if necessary**

**8. Expiry date**

EXP {MM/YYYY}

**9. Special storage conditions**

Store below 30°C, in a dry place protected from light.

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

300 mg/300 mg Tablets

(Macleods Pharmaceuticals Ltd.), HA514

**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**

India Macleods Pharmaceuticals Limited  
304, Atlanta Arcade,  
Marol Church road,  
Andheri (East),  
Mumbai – 400 059, India.  
Tel: +91-22-66762800  
Fax: +91 -22-29256229

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

HA514

**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 IMMEDIATE PACKAGING**

### **Bottle label**

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

[HA514 trade name]\* Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets

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

Each film-coated tablet contains Lamivudine 300 mg Tenofovir disoproxil fumarate 300 mg (equivalent to tenofovir disoproxil 245 mg or tenofovir 136 mg)

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

Contains 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.

Do not chew.

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 of children.

#### **7. Other special warning(s), if necessary**

#### **8. Expiry date**

EXP {MM/YYYY}

#### **9. Special storage conditions**

Store below 30°C, in a dry place protected from light.

#### **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**

India Macleods Pharmaceuticals Limited  
304, Atlanta Arcade,  
Marol Church road,  
Andheri (East),  
Mumbai – 400 059, India.  
Tel: +91-22-66762800  
Fax: +91 -22-29256229

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

HA514

**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**

[HA514 trade name]\* Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets

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

Each film-coated tablet contains Lamivudine 300 mg Tenofovir disoproxil fumarate 300 mg (equivalent to tenofovir disoproxil 245 mg or tenofovir 136 mg)

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

Contains lactose.

See patient information leaflet for further information.

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

Film-coated tablets

10 x 10's tablets

#### **5. Method and route of administration**

Oral use.

Do not chew.

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 of children.

#### **7. Other special warning(s), if necessary**

#### **8. Expiry date**

EXP {MM/YYYY}

#### **9. Special storage conditions**

Store below 25°C, in a dry place protected from light.

#### **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**

India Macleods Pharmaceuticals Limited  
304, Atlanta Arcade,  
Marol Church road,  
Andheri (East),  
Mumbai – 400 059, India.  
Tel: +91-22-66762800  
Fax: +91 -22-29256229

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

HA514

**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 STRIPS**

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

[HA514 trade name]\* Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets

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

India Macleods Pharmaceuticals Limited  
304, Atlanta Arcade,  
Marol Church road,  
Andheri (East),  
Mumbai – 400 059, India.  
Tel: +91-22-66762800  
Fax: +91 -22-29256229

### **3. Expiry date**

EXP {MM/YYYY}

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

<Batch> <Lot> {number}