

## **LABELLING**

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

Outer carton for blister

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

[HA535 trade name]\* Tenofovir disoproxil fumarate 300 mg film coated 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.

See patient information leaflet for further information.

### **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**

Do not store above 30°C. Protect from moisture.

### **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.

† Formerly Strides Shasun Limited.

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

Strides Pharma Science Limited  
Strides House, Opp. IIMB,  
Bilekahalli,  
Bannerghatta Road,  
Bangalore – 560 076  
INDIA.  
Tel: +91-80-67840738/215  
Email: AshokKumar.J@[strides.com](mailto:AshokKumar.J@strides.com)

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

HA535

**13. Manufacturer's batch number**

<Batch> {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**

Al/Al cold form blisters

**1. Name of the medicinal product**

[HA535 trade name] Tenofovir disoproxil fumarate 300 mg film coated tablets

Tenofovir disoproxil fumarate

**2. Name of the supplier**

Strides Pharma Science Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> {number}

**5. Other**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON IMMEDIATE PACKAGING**

Outer carton/HDPE bottle

**1. Name of the medicinal product**

[HA535 trade name]† Tenofovir disoproxil fumarate 300 mg film coated 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.

See patient information leaflet for further information.

**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**

Do not store above 30°C. Protect from moisture.

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

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INDIA.  
Tel: +91-80-67840738/215  
Email: AshokKumar.J@[strides.com](mailto:AshokKumar.J@strides.com)

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

HA535

**13. Manufacturer's batch number**

<Batch> {number}

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

Medicinal product subject to medical prescription.

**15. Instructions on use**

**MINIMUM PARTICULARS TO APPEAR ON HDPE bottle**  
HDPE bottle

**1. Name of the medicinal product**

[HA535 trade name]‡ Tenofovir disoproxil fumarate 300 mg film coated 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.

See patient information leaflet for further information.

**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**

Do not store above 30°C. Protect from moisture.

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

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Email: AshokKumar.J@[strides.com](mailto:AshokKumar.J@strides.com)

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

HA535

**13. Manufacturer's batch number**

<Batch> {number}

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

Medicinal product subject to medical prescription.

**15. Instructions on use**