

## **LABELLING**

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

### **Outer carton and bottle label/HDPE**

**1. Name of the medicinal product**

[HA286 trade name] \*

**2. Statement of active substance**

Each film-coated tablet contains 150 mg lamivudine and 300 mg zidovudine.

**3. List of excipients**

See patient information leaflet for further information.

**4. Pharmaceutical form and contents**

60 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 at or below 30°C. Store in the original package in order to protect from moisture.

**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**

Sun Pharmaceutical Industries Limited  
Sun House, 201 B/1  
Western Express Highway  
Goregaon (East)

---

† Formerly Ranbaxy Laboratories Ltd.

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

Mumbai 400 063  
India  
Tel. No.: (+91 22) 4324 4324  
Fax. No.: (+91 22) 4324 4343

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

HA286

**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  
Carton/Blisters (Alu-PA/PVC and Alu/PVC/PVdC)**

**1. Name of the medicinal product**

[HA286 trade name]

**2. Statement of active substance**

Each film-coated tablet contains 150 mg lamivudine and 300 mg zidovudine.

**3. List of excipients**

See patient information leaflet for further information.

**4. Pharmaceutical form and contents**

10x6 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 at or below 30°C. Store in the original package in order to protect from moisture.

**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**

Sun Pharmaceutical Industries Limited  
Sun House, 201 B/1  
Western Express Highway  
Goregaon (East)  
Mumbai 400 063  
India

Tel. No.: (+91 22) 4324 4324

Fax. No.: (+91 22) 4324 4343

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

HA286

**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  
Blister (Alu-PA/PVC and Alu/PVC/PVdC)**

**1. Name of the medicinal product**

[HA286 trade name]

**2. Name of the supplier**

Sun Pharmaceutical Industries Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**