

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING  
HDPE bottle label**

**1. Name of the medicinal product**

[HA657 trade name]\* Abacavir (as sulphate)/Lamivudine 600 mg/ 300 mg tablets  
Abacavir (as sulphate)/lamivudine

**2. Statement of active substance**

Each film coated tablet contains 600 mg of abacavir (as sulfate) and 300 mg lamivudine

**3. List of excipients**

Contains FD&C Yellow #6/Sunset Yellow FCF Aluminium Lake.  
See patient information leaflet for further information.

**4. Pharmaceutical form and contents**

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 and sight of children.

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

**Detach Alert Card enclosed in the pack, it contains important safety information**

WARNING! In case of any symptoms suggesting hypersensitivity reactions, contact your health care provider IMMEDIATELY.

**8. Expiry date**

EXP {MM/YYYY}

**9. Special storage conditions**

Do not store above 30°C. Do not remove the dessicant canister from the bottle.

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

**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**

Hetero Labs Limited  
7-2-A2, Hetero Corporate  
Industrial Estates  
Sanath Nagar, Hyderabad-500 018  
Telangana, India.

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

HA657

**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 AND IMMEDIATE PACKAGING**

### **Blister carton**

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

[HA657 trade name]<sup>†</sup> Abacavir (as sulphate)/Lamivudine 600 mg/ 300 mg tablets

Abacavir (as sulphate)/lamivudine

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

Each film coated tablet contains 600 mg of abacavir (as sulfate) and 300 mg lamivudine

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

Contains FD&C Yellow #6/Sunset Yellow FCF Aluminium Lake

See patient information leaflet for further information.

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

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 and sight of children.

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

**Detach Alert Card enclosed in the pack, it contains important safety information**

WARNING! In case of any symptoms suggesting hypersensitivity reactions, contact your health care provider IMMEDIATELY.

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

EXP {MM/YYYY}

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

Do not store above 30°C.

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

**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**

Hetero Labs Limited  
7-2-A2, Hetero Corporate  
Industrial Estates  
Sanath Nagar, Hyderabad-500 018  
Telangana, India.

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

HA657

**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**

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

[HA657 trade name] Abacavir (as sulphate)/Lamivudine 600 mg/ 300 mg tablets  
Abacavir (as sulphate)/lamivudine

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

Hetero Labs Ltd

### **3. Expiry date**

EXP {MM/YYYY}

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

<Batch> {number}