

## **LABELLING**

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

HDPE bottle carton

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

[HA662 trade name]\* Abacavir (as sulfate)/lamivudine 120 mg/60 mg dispersible tablets  
Abacavir (as sulfate)/lamivudine

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

Each uncoated dispersible tablet contains Abacavir Sulfate USP equivalent to Abacavir 120 mg and Lamivudine USP 60 mg

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

Contains aspartame, see patient information leaflet for further information.

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

Dispersible tablets

1 x 60 tablets

1 x 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**

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

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

### **8. Expiry date**

EXP {MM/YYYY}

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

Do not store above 30<sup>0</sup>C.

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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**

Cipla Limited Cipla House,  
Peninsula Business Park  
Ganpatrao Kadam Marg, Lower Parel Mumbai -400013,  
India  
Phone: 9122 24826000  
Fax: 9122 24826120

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

HA662

**13. Manufacturer's batch number**

<Batch> {number}

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

Medicinal product subject to medical prescription.

**15. Instructions on use**

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