

## **LABELLING**

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

Bottle and carton label

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

[HA353 trade name]\* Lamivudine 150 mg film-coated tablets

Lamivudine

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

Each film-coated tablet contains 150 mg lamivudine.

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

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

Film coated tablets

30 film-coated tablets

60 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. Store in the original container.

### **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.

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

Cipla Ltd.,  
Cipla House,  
Peninsula Business Park,  
Ganpatrao Kadam Marg, Lower Parel,  
Mumbai - 400 013,  
India

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

HA353

**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

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

[HA353 trade name]<sup>†</sup> Lamivudine 150 mg film-coated tablets

Lamivudine

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

Each film-coated tablet contains 150 mg lamivudine.

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

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

Film coated tablets

30 film-coated tablets

60 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. Store in the original container.

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

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

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

Cipla Ltd.,  
Cipla House,  
Peninsula Business Park,  
Ganpatrao Kadam Marg, Lower Parel,  
Mumbai - 400 013,  
India

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

HA353

**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**