

## **LABELLING**

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

Carton/HDPE bottle label

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

[HA424 trade name]\*Lamivudine150 mg tablets

Lamivudine

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

Each film-coated tablet contains 150 mg lamivudine.

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

See patient information leaflet for further information.

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

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 in a dry place and protected from light.

### **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**

Macleods Pharmaceuticals Limited,  
Atlanta Arcade, 3<sup>rd</sup> floor, Church Road, near Leela Hotel,  
Andheri-Kurla Road,  
Andheri (East),  
400 059 - Mumbai,  
India

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

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Email : [exports@macleodspharma.com](mailto:exports@macleodspharma.com)  
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[sjadhav@macleodspharma.com](mailto:sjadhav@macleodspharma.com)

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

HA424

**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**

Blister carton label

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

[HA424 trade name]<sup>†</sup> Lamivudine 150 mg tablets

Lamivudine

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

Each film-coated tablet contains 150 mg lamivudine.

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

See patient information leaflet for further information.

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

6 x 10 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**

Store below 30°C in a dry place and protected from light. Keep out of reach of children.

### **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**

Macleods Pharmaceuticals Limited,  
Atlanta Arcade, 3<sup>rd</sup> floor, Church Road, near Leela Hotel,  
Andheri-Kurla Road,  
Andheri (East),  
400 059 - Mumbai,

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

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

HA424

**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**

Blister label

**1. Name of the medicinal product**

[HA424 trade name] Lamivudine 150 mg tablets

Lamivudine

**2. Name of the supplier**

Macleods Pharmaceuticals Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch><Lot>{number}

**5. Other**