

## **LABELLING**

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

Outer carton

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

[HA410 trade name]\* Tenofovir disoproxil fumarate 300 mg tablets

Tenofovir disoproxil fumarate

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

Each film-coated tablet contains 300 mg tenofovir disoproxil fumarate equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir.

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

Contains Lactose

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

30 film-coated tablets

100 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. Protect 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**

Mylan Laboratories Limited

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

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Hyderabad – 500096  
Telangana  
India  
E-mail: [ProductSafety@viatris.com](mailto:ProductSafety@viatris.com)

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

HA410

**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**

HDPE bottle

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

[HA410 trade name]<sup>†</sup> Tenofovir disoproxil fumarate 300 mg tablets

Tenofovir disoproxil fumarate

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

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

Contains Lactose

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100 film-coated tablets

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