

## **LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING  
Plastic (HDPE) bottle**

**1. Name of the medicinal product**

[HA717 trade name]\* Emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

**2. Statement of active substance**

Each film-coated tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate.

**3. List of excipients**

Contains lactose.

See patient information leaflet for further information.

**4. Pharmaceutical form and contents**

Film-coated tablets

30 tablets

90 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**

**8. Expiry date**

EXP {MM/YYYY}

**9. Special storage conditions**

Do not store above 30°C. Store in the original container. Keep the bottle tightly closed.

**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 agency's responsibility.

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

Laurus Labs Limited  
2nd Floor, Serene Chambers, Road No.7  
Banjara hills, Hyderabad  
Telangana - 500034  
India

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

HA717

**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**