

Emtricitabine/tenofovir disoproxil fumarate  
200 mg/300 mg tablets  
(Micro Labs Ltd), HA631

WHOPAR part5

April 2020

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton label (blister and HDPE bottle)**

**1. NAME OF THE MEDICINAL PRODUCT**

[HA631 trade name]\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each film-coated tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

**3. LIST OF EXCIPIENTS**

Contains lactose.  
See the patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Alu-Alu blister: 10x3 film-coated tablets  
10x10 film-coated tablets

HDPE bottle: 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 out of the reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP {MM/YYYY}

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

**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**

**11. NAME AND ADDRESS OF THE SUPPLIER**

Micro Labs Limited  
# 31, Race Course Road  
Bangalore - 560001, Karnataka  
India  
Tel: +91-80-2237 0451 to 2237 0457  
Fax: +91-80-2237 0463

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

HA631

**13. MANUFACTURER'S BATCH NUMBER**

<Batch No >

**14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

**1. NAME OF THE MEDICINAL PRODUCT**

[HA631 trade name]

**2. NAME OF THE SUPPLIER**

Micro Labs Limited

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

<Batch No>