

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton box/HDPE bottle

- 1. Name of the medicinal product**
[HA620 trade name]¹ Lamivudine/Tenofovir Disoproxil Fumarate /300mg/300mg Tablets
- 2. Statement of active substance**
Each tablet contains 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (TDF) equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir.
- 3. List of excipients**
Contains lactose
See patient information leaflet for further information.
- 4. Pharmaceutical form and contents**
Film-coated tablets
30 tablets
100 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}
- 9. Special storage conditions**
Do not store above 30°C.
- 10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

11. Name and address of the supplier

Micro Labs Limited
31, Race Course Road
Bangalore - 560001, Karnataka,
India Tel: +91-80-2237 0451/57
Fax: +91-80-2237 0463

12. WHO Reference Number (Prequalification Programme)

HA620

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use