

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton box/HDPE bottle

- 1. Name of the medicinal product**
[HA666 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**
See patient information leaflet for further information.
- 4. Pharmaceutical form and contents**
Film-coated tablets
30 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

Cipla Limited
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India

12. WHO Reference Number (Prequalification Programme)

HA666

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use