

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA703 trade name]* Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

Lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-tablet contains 300 mg lamivudine and 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

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 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. 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

Lupin Limited

Kalpataru Inspire

3rd Floor, Off Western Express Highway

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

Lamivudine/tenofovir disoproxil fumarate
300 mg/300 mg tablets
(Lupin Limited), HA703

WHOPAR Part 5

November 2024

Santacruz (East), Mumbai
Maharashtra 400 055
India

12. WHO Reference Number (Prequalification Programme)

HA703

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