

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA715 trade name]* Emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

Emtricitabine/tenofovir disoproxil fumarate

2. Statement of active substance

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

3. List of excipients

Contains lactose monohydrate

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. Avoid excursions above 30°C.

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
Santacruz (East), Mumbai

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

Emtricitabine/tenofovir disoproxil fumarate
200 mg/300 mg tablets
(Lupin Limited), HA715

WHOPAR Part 5

January 2025

Maharashtra 400 055
India

12. WHO Reference Number (Prequalification Programme)

HA715

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