

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA726 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.

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.

Do not chew.

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. Store in a tightly closed container. Do not remove the silica gel canister from the bottle.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

11. Name and address of the supplier

Emcure Pharmaceuticals Limited
Plot No. P1 & P2, I.T.B.T. Park
Phase II., M.I.D.C., Hinjawadi,
Pune-411057,
Maharashtra, India

12. WHO Reference Number (Prequalification Programme)

HA726

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

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Outer carton

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