

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA726 trade name]*

Emtricitabine /Tenofovir disoproxil fumarate 200mg/300mg Tablets

2. Statement of active substance

Each film-coated tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate.

3. List of excipients

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 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

11. Name and address of the supplier

Emcure Pharmaceuticals Ltd

T-184, MIDC, Bhosari

Pune-411026

India

12. WHO Reference Number (Prequalification Programme)

HA726

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

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

See prescribing information for dosage information.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[HA726 trade name]

Emtricitabine /Tenofovir disoproxil fumarate 200 mg/300 mg Tablets

2. Statement of active substance

Each film-coated tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate.

3. List of excipients

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 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

11. Name and address of the supplier

Emcure Pharmaceuticals Ltd

T-184, MIDC, Bhosari

Pune-411026

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

See prescribing information for dosage information.