

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic (HDPE) bottle

1. Name of the medicinal product

[HA631 trade name]* Emtricitabine / tenofovir disoproxil fumarate 200 mg/300 mg tablets
Emtricitabine, tenofovir disoproxil fumarate

2. Statement of active substance

Each tablet contains 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate.

3. List of excipients

Each tablet also contains lactose.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets

100 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. Store in the original container.

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

Micro Labs Limited
31 Race Course Road
Bengaluru- 560001
Karnataka India

12. WHO Reference Number (Prequalification Programme)

HA631

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[HA631 trade name] Emtricitabine / tenofovir disoproxil fumarate 200 mg/300 mg tablets
Emtricitabine, tenofovir disoproxil fumarate

2. Statement of active substance

Each tablet contains 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate.

3. List of excipients

Each tablet also contains lactose.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

3 x 10 tablets

10 x 10 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. Store in the original container.

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

Micro Labs Limited
31 Race Course Road

Bengaluru - 560001
Karnataka India

12. WHO Reference Number (Prequalification Programme)

HA631

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Aluminium foil blisters

1. Name of the medicinal product

[HA631 trade name] Emtricitabine / tenofovir disoproxil fumarate 200 mg/300 mg tablets

2. Name of the supplier

Micro Labs Ltd.

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other