

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic (HDPE) bottle

1. Name of the medicinal product

[HA561 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

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

Store below 30°C, in a dry place, protected 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

Macleods Pharmaceuticals Limited

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

304, Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

HA561

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

[HA561 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
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

Store below 25°C, in a dry place, protected 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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road

Andheri (East)
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

HA561

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

[HA561 trade name] Emtricitabine / tenofovir disoproxil fumarate 200 mg/300 mg tablets
Emtricitabine, tenofovir disoproxil fumarate

2. Name of the supplier

Macleods Pharmaceutical Limited

3. Expiry date

4. Manufacturer's batch number

<Batch><Lot>{number}

5. Other