

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton/HDPE bottle label (White bottle with desiccant)

1. Name of the medicinal product

[HA417 trade name]*

Emtricitabine/tenofovir disoproxil fumarate 200mg/300 mg tablets

2. Statement of active substance

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

3. List of excipients

Contains lactose.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

28 film-coated tablets

30 film-coated tablets

100 film-coated 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 and sight 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 package. Do not remove desiccant from container.

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

† Formerly Matrix Laboratories Limited.

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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500096,
Telangana, India
Tel: +91 40 39258109
Email: Imtiyaz.Basade@mylan.in

12. WHO Reference Number (Prequalification Programme)

HA417

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

Carton/HDPE bottle label (Blue bottle with desiccant)

1. Name of the medicinal product

[HA417 trade name]

Emtricitabine/tenofovir disoproxil fumarate 200mg/300 mg tablets

2. Statement of active substance

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

3. List of excipients

Contains lactose.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

30 film-coated 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 the original package. Do not remove desiccant from 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

Mylan Laboratories Limited

Plot No. 564/A/22, Road No.92, Jubilee Hills

Emtricitabine/tenofovir disoproxil fumarate
200mg/300 mg tablets
(Mylan Labs Ltd†), HA417

WHOPAR Part 5

June 2020

Hyderabad - 500096,
Telangana, India
Tel: +91 40 39258109
Email: Imtiyaz.Basade@mylan.in

12. WHO Reference Number (Prequalification Programme)

HA417

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

Alu-Alu blister pack

1. Name of the medicinal product

[HA417 trade name]

Emtricitabine/tenofovir disoproxil fumarate 200mg/300 mg tablets

2. Statement of active substance

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

3. List of excipients

Contains lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

30 (3 x10) film-coated 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 and sight 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 package.

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

Mylan Laboratories Limited

Plot No. 564/A/22, Road No.92, Jubilee Hills

Emtricitabine/tenofovir disoproxil fumarate
200mg/300 mg tablets
(Mylan Labs Ltd†), HA417

WHOPAR Part 5

June 2020

Hyderabad - 500096,
Telangana, India
Tel: +91 40 39258109
Email: Imtiyaz.Basade@mylan.in

12. WHO Reference Number (Prequalification Programme)

HA417

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

Alu-Alu blister

1. Name of the medicinal product

[HA417 trade name]

Emtricitabine/tenofovir disoproxil fumarate 200mg/300 mg tablets

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other