

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HA679 trade name]* Tenofovir disoproxil fumarate 300 mg film coated tablets

Tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 300 mg of tenofovir disoproxil fumarate equivalent to 245 mg of tenofovir disoproxil.

3. List of excipients

Contains lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

30 Tablets

500 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

Laurus Labs Limited
2nd Floor, Serene Chambers,
Road 7, Banjara Hills, Hyderabad
Telangana, 500 034
India.

12. WHO Reference Number (Prequalification Programme)

HA679

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 HDPE bottle

HDPE bottle

1. Name of the medicinal product

[HA679 trade name][†] Tenofovir disoproxil fumarate 300 mg film coated tablets

Tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 300 mg of tenofovir disoproxil fumarate equivalent to 245 mg of tenofovir disoproxil.

3. List of excipients

Contains lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

30 Tablets

500 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

Laurus Labs Limited
2nd Floor, Serene Chambers,
Road 7, Banjara Hills, Hyderabad
Telangana, 500 034
India.

12. WHO Reference Number (Prequalification Programme)

HA679

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