

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[HA448 trade name]* Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

Lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-tablet contains 300 mg lamivudine and 300mg tenofovir disoproxil fumarate
(equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir)

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets

60 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. Protect from light.

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

M/S Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates, Sanath Nagar
Telangana-500 018
India

12. WHO Reference Number (Prequalification Programme)

HA448

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 IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA448 trade name][†] Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

Lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-tablet contains 300 mg lamivudine and 300mg tenofovir disoproxil fumarate
(equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir)

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets

60 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. Protect from light.

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

M/S Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates, Sanath Nagar
Telangana-500 018
India

12. WHO Reference Number (Prequalification Programme)

HA448

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