

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle label

1. Name of the medicinal product

[HA514 trade name]* Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets
Lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg (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

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

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

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)

HA514

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 of the bottle/blister

1. Name of the medicinal product

[HA514 trade name] Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

Lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

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

3. List of excipients

Contains lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

Bottle: 30 tablets

Blister: 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

Bottle: Store below 30°C, in a dry place, protected from light.

Blister: 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)

HA514

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

Blisters

1. Name of the medicinal product

[HA514 trade name] Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other