LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[HA525 trade name][*]
Lamivudine/Tenofovir disoproxil fumarate 300 mg/300 mg Tablets

2. Statement of active substance

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

3. List of excipients

Contains lactose.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets
30 tablets
90 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 30ºC. Protect from moisture.

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

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1
Western Express Highway
Goregaon (East)
Mumbai – 400063
India

12. WHO Reference Number (Prequalification Programme)

HA525

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

[HA525 trade name][†]
Lamivudine/Tenofovir disoproxil fumarate 300 mg/300 mg Tablets

2. Statement of active substance

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

3. List of excipients

Contains lactose.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets
30 tablets
90 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 30ºC. Protect from moisture.

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

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1

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

Western Express Highway
Goregaon (East)
Mumbai – 400063
India

12. WHO Reference Number (Prequalification Programme)

HA525

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