LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton for blister

1. Name of the medicinal product

[HA535 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

Film-coated tablets

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 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 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.
† Formerly Strides Shasun Limited.

11. Name and address of the supplier

Strides Pharma Science Limited
Strides House, Opp. IIMB,
Bilekahalli,
Bannerghatta Road,
Bangalore – 560 076
INDIA.
Tel: +91-80-67840000
Email: corpcomm@strides.com

12. WHO Reference Number (Prequalification Programme)

HA535

13. Manufacturer's batch number

<Batch>{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

Al/Al cold form blisters

1. Name of the medicinal product

[HA535 trade name] Tenofovir disoproxil fumarate 300 mg film coated tablets

Tenofovir disoproxil fumarate

2. Name of the supplier

Strides Pharma Science Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch>{number}

5. Other

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON IMMEDIATE PACKAGING

Outer carton/HDPE bottle

1. Name of the medicinal product

[HA535 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

Film-coated tablets

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 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 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.
† Formerly Strides Shasun Limited.

11. Name and address of the supplier

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Tel: +91-80-67840000
Email: corpcomm@strides.com

12. WHO Reference Number (Prequalification Programme)

HA535

13. Manufacturer's batch number

<Batch> {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

[HA535 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

Film-coated tablets

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 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 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.
† Formerly Strides Shasun Limited.

11. Name and address of the supplier

Strides Pharma Science Limited
Strides House, Opp. IIMB,
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INDIA.
Tel: +91-80-67840000
Email: corpcomm@strides.com

12. WHO Reference Number (Prequalification Programme)

HA535

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use