

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton

1. Name of the medicinal product

[HA516 trade name] ^{*}Tenofovir disoproxil fumarate 300 mg tablets

Tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 300 mg 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

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

Store at a temperature not exceeding 30°C. Protect from moisture.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

No special requirements

11. Name and address of the supplier

Macleods Pharmaceuticals Limited
304 Atlanta Arcade
Marol Church Road
Andheri (East)

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

Mumbai 400 059
India.
Tel: + 91 22 66762800
Fax: + 91 22 28216599
E-mail: exports@macleodspharma.com
vijay@macleodspharma.com
sjadhav@macleodspharma.com

12. WHO Reference Number (Prequalification Programme)

HA516

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

1. Name of the medicinal product

[HA516 trade name][†] Tenofovir disoproxil fumarate 300 mg tablets

Tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 300 mg 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

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

Store at a temperature not exceeding 30°C. Protect from moisture.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

No special requirements

11. Name and address of the supplier

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12. WHO Reference Number (Prequalification Programme)

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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