

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton label

1. NAME OF THE MEDICINAL PRODUCT

[HA516 trade name]*

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. See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 film-coated tablets.

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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 and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

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

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)
Mumbai 400 059
INDIA.
Tel: + 91 22 66762800
Fax: + 91 22 28216599
sjadhav@macleodspharma.com

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA516

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {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

Bottle label

1. NAME OF THE MEDICINAL PRODUCT

[HA516 trade name]

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. See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 film-coated tablets.

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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 and sight 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

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