LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton/bottle label (HDPE bottle)

1. NAME OF THE MEDICINAL PRODUCT

Lamivudine/Tenofovir Disoproxil Fumarate Tablets 300 mg/300 mg [*]

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 136 mg of tenofovir.

3. LIST OF EXCIPIENTS

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 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 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 (NMRA) responsibility. Throughout this WHOPAR the Proprietary Name is given as an example only.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC.

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

Cipla Limited
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA666

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label/Blisters (Alu-Alu)

1. NAME OF THE MEDICINAL PRODUCT

Lamivudine/Tenofovir Disoproxil Fumarate Tablets 300 mg/300 mg[†]

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 136 mg of tenofovir.

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

3x10 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 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 (NMRA) responsibility. Throughout this WHOPAR the Proprietary Name is given as an example only.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC.

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

Cipla Limited
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA666

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Lamivudine/Tenofovir Disoproxil Fumarate Tablets 300 mg/300 mg[‡]

2. NAME OF THE SUPPLIER

Cipla Limited

3. EXPIRY DATE

EXP {DD/MM/YYYY}

4. BATCH NUMBER

<Batch> {number}

[‡] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the Proprietary Name is given as an example only.