LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label (blister and HDPE bottle)

1. NAME OF THE MEDICINAL PRODUCT

Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets[1]

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 200 mg emtricitabine and 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

Alu-Alu blister: 10x 3 or 10x10 film coated tablets

HDPE bottle: 30 or 100 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

[1]Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store below 30°C. Store in original container.

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

Micro Labs Limited
27, Race Course Road
Bangalore - 560001, Karnataka
India
Tel: +91-80-2237 0451 to 2237 0457
Fax: +91-80-2237 0463

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA631

13. MANUFACTURER'S BATCH NUMBER

<Batch No >

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets

2. NAME OF THE SUPPLIER

Micro Labs Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch No>