LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING
Carton box/HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600 mg / 300 mg/300 mg Tablets*

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 600 mg efavirenz, 300 mg lamivudine 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

30 Tablets

5. METHOD AND ROUTE(S) 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

9. SPECIAL STORAGE CONDITIONS

Store below 30°C, in a dry place. Protect from light.

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. Throughout this WHOPAR the proprietary name is given as an example only.

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 -22-29256229

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA611

13. BATCH NUMBER

<Batch> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE