LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA714 trade name][*] Efavirenz/lamivudine/tenofovir disoproxil fumarate 400 mg/300 mg/300 mg tablets
Efavirenz/lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each tablet contains 400 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Film-coated tablet

30 tablets

90 tablets

180 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

Do not store above 30°C. Protect from light. Avoid excursions above 30°C.

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.

11. Name and address of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

HA714

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