

LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

HDPE bottle/Carton

1. Name of the medicinal product

[HA767 trade name]* efavirenz/lamivudine/tenofovir disoproxil fumarate 600mg/300mg/300mg tablets

Efavirenz/lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 600 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate.

3. List of excipients

Each tablet contains lactose monohydrate and sodium.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

30 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 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.

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

Supplier

Micro Labs Limited
31, Race Course Road,
Bangalore - 560001, Karnataka, India.

12. WHO Reference Number (Prequalification Programme)

HA767

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