

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle and carton label (white or blue HDPE bottle)

1. Name of the medicinal product

[HA466 trade name]*

Efavirenz/lamivudine/tenofovir disoproxil fumarate 600 mg/300 mg/300 mg tablets

2. Statement of active substance

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 and sodium.

4. Pharmaceutical form and contents

Film-coated tablets

30 film-coated tablets

90 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 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. Store in the original container. 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.

11. Name and address of the supplier

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad – 500096
Telangana, INDIA

12. WHO Reference Number (Prequalification Programme)

HA466

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