

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA444 trade name]* Efavirenz/emtricitabine/tenofovir disoproxil fumarate
600 mg/200 mg/300 mg tablets
Efavirenz/emtricitabine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 600 mg efavirenz, 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

4. Pharmaceutical form and contents

Film-coated tablets
30 film-coated tablets
28 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

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Store in the original container. Keep the container tightly closed.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Formerly known as 'Matrix Laboratories Limited'

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

Mylan Laboratories Limited,
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500096, Telangana,
India
[Email: ProductSafety@viatris.com](mailto:ProductSafety@viatris.com)

12. WHO Reference Number (Prequalification Programme)

HA444

13. Manufacturer's batch number

Batch {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use