

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE AND OUTER PACKAGING

HDPE bottle/Carton

1. Name of the medicinal product

[HA553 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).

3. List of excipients

Contains lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

28 film-coated tablets

30 film-coated tablets

84 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 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. Keep in a tightly closed container.

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

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

Strides Pharma Science Limited
Strides House, Bilekahalli
Bannerghatta Road
Bangalore – 560 076
India

12. WHO Reference Number (Prequalification Programme)

HA553

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

As directed by the health care provider