

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE

1. Name of the medicinal product

[HA766 trade name]*

Efavirenz/lamivudine/tenofovir disoproxil fumarate 400 mg / 300 mg/300 mg tablets

2. Statement of active substance

Each tablet contains 400 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (TDF) equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir.

3. List of excipients

Contains lactose monohydrate

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. Avoid excursions above 30°C.

Discard after date

* 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

Desano Pharmaceuticals Private Limited
No. 77D, KIADB Industrial Area,
Jigani, Bengaluru,
Karnataka- 560105,
India

12. WHO Reference Number (Prequalification Programme)

HA766

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