

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE

1. Name of the medicinal product

[HA593 trade name]* Efavirenz/Lamivudine/Tenofovir disoproxil fumarate
600mg/300mg/300mg tablets

2. Statement of active substance

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

3. List of excipients

The tablets also contain lactose.
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 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.

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

Cipla Ltd.
Cipla House, Peninsula Business Park,
Ganpatrao Kadam Marg, Lower Parel,
Mumbai - 400 013, India

12. WHO Reference Number (Prequalification Programme)

HA593

13. Manufacturer's batch number

<Batch> <Lot> {number}

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

14. (Advice on) General classification for supply
Medicinal product subject to medical prescription.

15. Instructions on use

