

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA770 trade name]* Efavirenz/lamivudine/tenofovir disoproxil fumarate 400 mg/ 300 mg/
300 mg tablets
Efavirenz/lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 400 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate

3. List of excipients

Contain lactose monohydrate

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets

90 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.

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

Cipla Ltd,
Cipla House,
Peninsula Business Park,
Ganpatrao Kadam Marg,
Lower Parel,
Mumbai-400013,
India

12. WHO Reference Number (Prequalification Programme)

HA770

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