

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA756 trade name]* efavirenz/lamivudine/tenofovir disoproxil fumarate 600mg/300mg/300mg tablets

Efavirenz/lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each tablet contains efavirenz 600 mg, lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

List of excipients

Contains Lactose and sodium

See patient information leaflet for further information.

3. Pharmaceutical form and contents

Film coated tablets

1×90's

1×30's

4. Method and route of administration

Oral use.

Do not chew.

Read the patient information leaflet before use.

5. 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.

6. Other special warning(s), if necessary

7. Expiry date

EXP {MM/YYYY}

8. Special storage conditions

Do not store above 30°C

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

9. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

10. Name and address of the supplier

Celltrion, Inc.
23 Academy-ro,
Yeonsu-gu,
Incheon 22014
Republic of Korea

11. WHO Reference Number (Prequalification Programme)

HA756

12. Manufacturer's batch number

<Batch> <Lot> {number}

13. (Advice on) General classification for supply

Medicinal product subject to medical prescription.