

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE AND OUTER PACKAGING

HDPE bottle/Carton

1. Name of the medicinal product

[HA549 trade name]* efavirenz/lamivudine/tenofovir disoproxil fumarate 600mg/300mg/300mg tablets

Efavirenz/lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

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

3. List of excipients

Each tablet contains anhydrous lactose

See patient information leaflet for further information.

4. Pharmaceutical form and contents

30 film-coated tablets

90 film-coated tablets

100 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

Store below 30°C.

* 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

Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates
Sanath Nagar
Hyderabad – 500 018
Telangana
India

12. WHO Reference Number (Prequalification Programme)

HA549

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