

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton and bottle labels (HDPE bottle)

1. Name of the medicinal product

[HA562 trade name]*

Efavirenz/emtricitabine/tenofovir disoproxil fumarate tablets 600 mg /200 mg /300 mg film-coated tablets.

2. Statement of active substance

Each film-coated tablet contains 600 mg efavirenz, 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

30 film-coated tablets

90 film-coated tablets

180 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 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

Store below 30°C, in dry place protected from light.

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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

HA562

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