LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA551 trade name][*] Emtricitabine /tenofovir disoproxil fumarate 200 mg/300 mg tablets

Emtricitabine/tenofovir disoproxil fumarate

2. Statement of active substance

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

3. List of excipients

Each tablet contains lactose.

See the patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablet

30 film-coated tablets

90 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

Do not store above 30°C. Protect from moisture. Store in the original container.

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

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1
Western Express Highway
Goregaon (East)
Mumbai – 400063
India

12. WHO Reference Number (Prequalification Programme)

HA551

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