LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

Carton and bottle label (HDPE bottle)

1. NAME OF THE MEDICINAL PRODUCT

[HA551 trade name][*]

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 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

Contains lactose.
See the patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

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 out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
† Formerly Ranbaxy Laboratories Limited.

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C, protect from moisture.

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

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> <BN> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE