LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle label

1. NAME OF THE MEDICINAL PRODUCT

[HA703 trade name]*

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 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

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

4. PHARMACEUTICAL FORM AND CONTENTS

30 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}

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

9. SPECIAL STORAGE CONDITIONS

Store at a temperature not exceeding 30°C. Protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

No special requirements.

11. NAME AND ADDRESS OF THE SUPPLIER

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East), Mumbai
Maharashtra 400 055
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA703

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