

LABELLING

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

HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

[HA715 trade name]*

2. STATEMENT OF ACTIVE SUBSTANCE

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

3. LIST OF EXCIPIENTS

Contains lactose monohydrate
See 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

Do not store above 30°C, protect from light. Avoid excursions above 30°C.

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

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

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA715

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