LABELING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Label/ white HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

[HA712 trade name][*]

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg

3. LIST OF EXCIPIENTS

Contains lactose monohydrate
See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 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.

Unused tablets should be discarded 90days after first opening of the bottle. When the bottle is first opened this "Discard after date" should be written on the bottle label in the place provided

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. 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

Celltrion Inc
23 Academy-ro,
Yeonsu-gu,
Incheon 22014
Republic of Korea.

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA712

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE