LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA752 trade name] * Dolutegravir Sodium/Lamivudine/Tenofovir disoproxil fumarate 50 mg/300 mg/300 mg tablets

Dolutegravir (as sodium) /lamivudine/ tenofovir disoproxil fumarate

2. Statement of active substance

Each tablet contains 50 mg dolutegravir (as sodium), 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate.

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.

90s bottle

Should be used within 90 days once opened.

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

Discard after {DD/MM/YY}

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)

HA752

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