LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA737 trade name][*] Dolutegravir/lamivudine/tenofovir disoproxil fumarate 50mg/300mg/300mg tablets

Dolutegravir/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

Contain lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets
60 tablets
90 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. Store and dispense in original bottle, protect from moisture and keep bottle tightly closed. Do not remove desiccant.

90's HDPE Container
Should be used within 90 days, once opened.

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

60's HDPE Container
Should be used within 60 days, once opened.

30's HDPE Container
Should be used within 30 days, once opened.

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 400055
India

12. WHO Reference Number (Prequalification Programme)

HA737

13. Manufacturer's batch number

<Batch>{number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use