LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA707 trade name]* Dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate 50mg/300mg/300mg tablets

Dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate

2. Statement of active substance

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

3. List of excipients

Each tablet contains mannitol and lactose monohydrate.

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets

30 Tablets

90 Tablets

180 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}

9. Special storage conditions

Do not store above 30°C. Store in the original container. Discard the product 90 days after first opening.

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

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

Laurus Labs Limited

2nd Floor, serene Chambers, Road No.7

Banjara hills, Hyderabad, Telangana- 500034

India

12. WHO Reference Number (Prequalification Programme)

HA707

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