LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA688 trade name][*] Dolutegravir (as 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 film-coated tablet contains 50 mg dolutegravir (as sodium), 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

3. List of excipients

Contains mannitol and lactose monohydrate

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 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 in the original container. Discard 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

Mylan Laboratories Limited
Plot No.564/A/22, Road No. 92, Jubilee Hills
Hyderabad – 500096
Telangana
India

12. WHO Reference Number (Prequalification Programme)

HA688

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