LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA755 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 tablet contains 50 mg dolutegravir (as sodium), 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate.

3. List of excipients

The tablets also contain lactose, sodium and mannitol

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 this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

Date opened {D D/M M/Y Y Y Y}

30's HDPE Container: Used within 30 days, once opened

90's HDPE Container: Use within 90 days once opened

180's HDPE Container: Use within 180 days once opened

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

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

Micro Labs Limited

31, Race Course Road

Bengaluru– 560001

Karnataka, India.

12. WHO Reference Number (Prequalification Programme)

HA755

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