LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle label

1. Name of the medicinal product

[HA713 trade name][1] 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 equivalent to 52.6 mg dolutegravir sodium, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (TDF) equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir.

3. List of excipients

Each film-coated tablet contains about 15.4 mg (0.67mmol) of sodium and 120 mg of mannitol.

4. Pharmaceutical form and contents

30 film-coated tablets

90 film-coated tablets

100 film-coated tablets

180 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, protect from light. Store in the original container. Avoid excursions above 30°C.

90 film-coated tablets: Should be used within 90 days once opened.

100 film-coated tablets: Should be used within 100 days once opened.

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

180 film-coated tablets: Should be used within 180 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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, India.

12. WHO Reference Number (Prequalification Programme)

HA713

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use