LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle / Carton label

1. Name of the medicinal product

[HA729 trade name][1] Dolutegravir/Lamivudine/Tenofovir disoproxil fumarate 50mg/300mg/300mg tablets

Dolutegravir/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.

3. List of excipients

Each tablet contains mannitol and lactose monohydrate.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

28 tablets
30 tablets
56 tablets
60 tablets
84 tablets
90 tablets
168 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 sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

[1] 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.

Discard 90 days after first opening. (This is only applicable to pack size of 90)

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

Strides Pharma Science Limited
Strides House, Opp IIMB, Bilekahalli,
Bannerghatta Road, Bangalore
Karnataka - 560 076,
India

12. WHO Reference Number (Prequalification Programme)

HA729

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use