LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
HDPE bottle

1. Name of the medicinal product

[HA702 trade name][*]

Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil fumarate 50mg/300mg/300mg tablets

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

Contains mannitol

4. Pharmaceutical form and contents

Film-coated tablets

28 tablets
30 tablets
84 tablets
90 tablets
180 tablets
500 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. *(This is only applicable to pack sizes of 90 and 500).*

Discard 180 days after first opening. *(This is only applicable to pack size of 180).*

[*] 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

Cipla Limited
Cipla House, Peninsula Business Park
Ganpatrao, Kadam Marg, Lower Parel
Mumbai, Maharashtra 400013
India

12. WHO Reference Number (Prequalification Programme)

HA702

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