

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA680 trade name]*

Dolutegravir (as sodium) 50 mg tablets

2. Statement of active substance

Each film-coated tablet contains 50 mg Dolutegravir (as sodium)

3. List of excipients

Contains mannitol and sodium

See patient information leaflet for further information.

4. Pharmaceutical form and contents

30 film-coated tablets

90 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 out of the reach and sight 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.

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 Ltd.

Cipla House

Peninsula Business Park

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

Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India

12. WHO Reference Number (Prequalification Programme)

HA680

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