

## **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  
Dolutegravir (as sodium)

**2. Statement of active substance**

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

**3. List of excipients**

Contains mannitol

**4. Pharmaceutical form and contents**

Film-coated tablets  
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 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.

**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

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\* 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**