

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**  
**Outer Carton**

**1. Name of the medicinal product**

[HA731 trade name]\* Dolutegravir (as sodium) 50 mg Tablets

**2. Statement of active substance**

Each film-coated tablet contains 50 mg dolutegravir

**3. List of excipients**

Contains mannitol

This medicine is essentially “sodium-free”.

See patient information leaflet for further information

**4. Pharmaceutical form and contents**

Film-coated Tablets

28 Tablets

30 Tablets

56 Tablets

60 Tablets

84 Tablets

90 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 of children.

**7. Other special warning(s), if necessary**

**8. Expiry date**

EXP {MM/YYYY}

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\* 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.

**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, Bilekahali,  
Bannerghatta Road, Bangalore  
Karnataka, 560 076  
India  
Tel: +91-80-67840738/290  
Email: info@strides.com

**12. WHO Reference Number (Prequalification Programme)**

HA731

**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**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING  
HDPE Bottle**

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