

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

HDPE bottle

### **1. Name of the medicinal product**

[HA765 trade name]\* Dolutegravir (as sodium) 10 mg dispersible tablets  
Dolutegravir (as sodium)

### **2. Statement of active substance**

Each dispersible tablet contains 10 mg dolutegravir (as sodium)

### **3. List of excipients**

Contains mannitol

### **4. Pharmaceutical form and contents**

Dispersible tablets

30 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 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 package to protect from moisture. Keep the bottle tightly closed. Avoid excursions above 30°C

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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

**11. Name and address of the supplier**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059  
India

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

HA765

**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**