

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
HDPE Bottle

1. Name of the medicinal product

[HA751 trade name]* Dolutegravir (as sodium) 50 mg Film-coated Tablets

2. Statement of active substance

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

3. List of excipients

Contains sodium and D-mannitol.

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated Tablets

30 Tablets

60 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}

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

Micro Labs Ltd
31, Race Course Road
Bengaluru- 560001
Karnataka
India
Tel: +91-80-22370451 to 22370457
Fax: +91-80-22370463

12. WHO Reference Number (Prequalification Programme)

HA751

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