

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label/HDPE Bottle label

1. Name of the medicinal product

[HA701 trade name]*

Dolutegravir (as sodium) 50mg tablets

2. Statement of active substance

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

3. List of excipients

Contains mannitol

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

30 Tablets

90 Tablets

180 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

Emcure Pharmaceuticals Limited

T-184, MIDC, Bhosari,
Pune 411026
India

12. WHO Reference Number (Prequalification Programme)

HA701

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

See prescribing information for dosage information