

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA694 trade name]*

Dolutegravir 50 mg film-coated tablets

2. Statement of active substance

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

3. List of excipients

Each tablet contains sodium and mannitol.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablet

30 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

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

11. Name and address of the supplier

Shanghai Desano Bio-Pharmaceutical Co Ltd
1479 Zhangheng Road
China (Shanghai) Pilot Free Trade Zone
Shanghai 201203
P.R. China

12. WHO Reference Number (Prequalification Programme)

HA694

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