LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer Carton

1. Name of the medicinal product

[HA731 trade name][*] Dolutegravir (sodium) 50mg film-coated tablets

Dolutegravir (sodium)

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

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 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.

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

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>{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

1. Name of the medicinal product

[HA731 trade name][†] Dolutegravir (sodium) 50mg film-coated tablets

Dolutegravir (sodium)

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

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 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.

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

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