LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[HA682 trade name][*]
Dolutegravir (as sodium) 50 mg tablets

2. Statement of active substance

Each tablet contains 50 mg Dolutegravir (as sodium)

3. List of excipients

Contains mannitol and sodium.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets
8 x 10 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 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 container

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

Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates
Sanath Nagar, Hyderabad-500 018
Telangana, India

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

12. WHO Reference Number (Prequalification Programme)

HA682

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA682 trade name][†]
Dolutegravir (as sodium) 50 mg tablets

2. Statement of active substance

Each tablet contains 50 mg Dolutegravir (as sodium)

3. List of excipients

Contains mannitol and sodium.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated 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 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 container

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

Hetero Labs Limited
7-2-A2, Hetero Corporate
Industrial Estates
Sanath Nagar, Hyderabad-500 018

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

Telangana, India

12. WHO Reference Number (Prequalification Programme)

HA682

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

ALU-ALU Blister

1. Name of the medicinal product

[HA682 trade name]
Dolutegravir (as sodium) 50 mg tablets

2. Name of the supplier

Hetero Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other