

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

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

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 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. Store in the original container

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.
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11. Name and address of the supplier

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

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

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 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. Store in the original container

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.
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11. Name and address of the supplier

Hetero Labs Limited
7-2-A2, Hetero
Industrial Estates
Sanath Nagar, Hyderabad-500 018
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 OR STRIP
ALU-ALU BLISTER

1. Name of the medicinal product

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

2. Name of the supplier

Hetero Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other