

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[HA794 trade name]* Dolutegravir (as sodium) 50 mg tablets
Dolutegravir (as sodium)

2. Statement of active substance

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

3. List of excipients

Contains mannitol

4. Pharmaceutical form and contents

Film-coated tablets
3 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. Avoid excursions 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

RV Lifesciences Limited
Plot No. H-19, MIDC, Waluj
Chhatrapati Sambhajanagar – 431133

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

12. WHO Reference Number (Prequalification Programme)

HA794

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

[HA794 trade name][†] Dolutegravir (as sodium) 50 mg tablets
Dolutegravir (as sodium)

2. Statement of active substance

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

3. List of excipients

Contains mannitol

4. Pharmaceutical form and contents

Film-coated tablets
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 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. Avoid excursions 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

RV Lifesciences Limited
Plot No. H-19, MIDC, Waluj
Chhatrapati Sambhajanagar – 431133

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Maharashtra State
India

12. WHO Reference Number (Prequalification Programme)

HA794

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 foil blisters

1. Name of the medicinal product

[HA794 trade name] Dolutegravir (as sodium) 50 mg tablets
Dolutegravir (as sodium)

2. Name of the supplier

RV Lifesciences Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other