LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Outer Carton

1. Name of the medicinal product

[HA708 trade name][*]

Dolutegravir (as sodium) 50 mg tablets

2. Statement of active substance

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

3. List of excipients

Contains mannitol

This medicine is essentially "sodium-free".

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tables

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 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.

Discard 30 days after first opening. *(30-tablet pack size)*

Discard 90 days after first opening. *(90-tablet pack size)*

[*] 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

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1
Western Express Highway
Goregaon (East)
Mumbai 400 063
India

12. WHO Reference Number (Prequalification Programme)

HA708

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

See prescribing information for dosage information

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA708 trade name]

Dolutegravir (as sodium) 50 mg tablets

2. Statement of active substance

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

3. List of excipients

Contains mannitol

This medicine is essentially “sodium-free”.

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tables

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 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.

Discard 30 days after first opening. *(30-tablet pack size)*
Discard 90 days after first opening. *(90-tablet pack size)*

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

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1
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Medicinal product subject to medical prescription.

15. Instructions on use

See prescribing information for dosage information