LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton(blisters)

1. Name of the medicinal product

[HA678 trade name]* Dolutegravir (as sodium) 50 mg film-coated tablets

Dolutegravir sodium

2. Statement of active substance

Each film-coated tablet contains dolutegravir sodium equivalent to 50 mg dolutegravir.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

1×10 tablets

5. Method and route of administration

Oral use.

Do not chew.

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.

11. Name and address of the supplier

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad – 500096, Telangana
India

12. WHO Reference Number (Prequalification Programme)

HA678

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 OUTER PACKAGING

Bottles (HDPE)

1. Name of the medicinal product

[HA678 trade name][†] Dolutegravir (as sodium) 50 mg film-coated tablets

Dolutegravir sodium

2. Statement of active substance

Each film-coated tablet contains dolutegravir sodium equivalent to 50 mg dolutegravir.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets

90 tablets

180 tablets

5. Method and route of administration

Oral use.

Do not chew.

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.

11. Name and address of the supplier

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad – 500096, Telangana
India

12. WHO Reference Number (Prequalification Programme)

HA678

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

Blisters

1. Name of the medicinal product

[HA678 trade name] dolutegravir (as sodium) 50 mg film-coated tablets

Dolutegravir sodium

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other