LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[HA701 trade name][*] Dolutegravir (sodium) 50mg film-coated tablets

Dolutegravir (sodium)

2. Statement of active substance

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

3. List of excipients

Contains mannitol. 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.

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.

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

Emcure Pharmaceuticals Limited

Plot No. P1 & P2, I.T.B.T. Park Phase II., M.I.D.C.,

Hinjawadi, Pune-411057, Maharastra, India

12. WHO Reference Number (Prequalification Programme)

HA701

13. Manufacturer's batch number

<Batch>{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

HDPE Bottle label

1. Name of the medicinal product

[HA701 trade name][†] Dolutegravir (sodium) 50mg film-coated tablets

Dolutegravir (sodium)

2. Statement of active substance

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

3. List of excipients

Contains mannitol. 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.

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.

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

Emcure Pharmaceuticals Limited

Plot No. P1 & P2, I.T.B.T. Park Phase II., M.I.D.C.,

Hinjawadi, Pune-411057, Maharastra, India

12. WHO Reference Number (Prequalification Programme)

HA701

13. Manufacturer's batch number

<Batch>{number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use