LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[HA722 trade name][*] Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil fumarate

50 mg/300 mg/300 mg tablets

Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 50 mg dolutegravir, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate

3. List of excipients

Contains mannitol and lactose monohydrate

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, MIDC, Hinjawadi
Pune- 411057
Maharashtra
India
Tel: 91-20-30610000

12. WHO Reference Number (Prequalification Programme)

HA722

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

[HA722 trade name][†] Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil fumarate 50 mg/300 mg/300 mg tablets

Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 50 mg dolutegravir, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate

3. List of excipients

Contains mannitol and lactose monohydrate

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, MIDC, Hinjawadi
Pune- 411057
Maharashtra
India

12. WHO Reference Number (Prequalification Programme)

HA722

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