

LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

HDPE bottle/Carton

1. Name of the medicinal product

[HA722 trade name]* Dolutegravir/Lamivudine/tenofovir disoproxil fumarate 50 mg/ 300 mg/ 300 mg tablets

Dolutegravir/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

Each tablet contains lactose monohydrate.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

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 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.

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
T-184, MIDC, Bhosari
Pune, 411026
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