

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA793 trade name]* Dolutegravir (as sodium) 10 mg dispersible tablets

Dolutegravir (as sodium)

2. Statement of active substance

Each film-coated tablet contains 10 mg dolutegravir (as sodium)

3. List of excipients

Contains mannitol

4. Pharmaceutical form and contents

Dispersible tablet

30 tablets

60 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 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

11. Name and address of the supplier

Micro Labs Limited

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

#31, Race Course Road
Bengaluru – 560 001
Karnataka
India

12. WHO Reference Number (Prequalification Programme)

HA793

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