Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil
fumarate 50mg/300mg/300mg tablets
(Lupin Ltd), HA737

WHOPAR Part 5

February 2023

LABELLING

Dolutegravir (as sodium)/lamivudine/tenofovir disoproxil   WHOPAR Part 5   February 2023
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PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
HDPE bottle

1. **Name of the medicinal product**
   [HA737 trade name]* Dolutegravir/Lamivudine/Tenofovir disoproxil fumarate
   50mg/300mg/300mg tablets

2. **Statement of active substance**
   Each tablet contains 50 mg dolutegravir (as sodium), 300 mg lamivudine and 300 mg tenofovir
   disoproxil fumarate.

3. **List of excipients**
   The tablets also contain lactose.
   See patient information leaflet for further information.

4. **Pharmaceutical form and contents**
   Film-coated tablets

   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}
   Discard after date DD/MM/YYYY

   90's HDPE Container
   Should be used within 90 days, once opened.

   60's HDPE Container
   Should be used within 60 days, once opened.

   30's HDPE Container
   Should be used within 30 days, once opened.

9. **Special storage conditions**
   Do not store above 30°C. Store and dispense in original bottle, protect from moisture and keep
   bottle tightly closed. Do not remove desiccant.

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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
Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East), Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)
HA737

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