

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. NAME OF THE MEDICINAL PRODUCT

[HA696 trade name]¹

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 50 mg dolutegravir (as sodium), 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate.

3. LIST OF EXCIPIENTS

Each film -coated tablet contains mannitol.
See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets

30 Tablets

60 Tablets

90 Tablets

100 Tablets

180 Tablets

750 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 and sight of children.

¹Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store in the original container.

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

Hetero Labs Limited
Hetero Corporate
7-2-A2, Industrial Estates
Sanath Nagar
Hyderabad
Telangana, 500 018
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA696

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE