LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

Carton and bottle label (HDPE bottle)

1. NAME OF THE MEDICINAL PRODUCT

[HA498 trade name][1]

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

3. LIST OF EXCIPIENTS

Contains lactose.
See the patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

28 Tablets
30 Tablets
56 Tablets
60 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.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

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

9. SPECIAL STORAGE CONDITIONS

Store below 30ºC, protect from light and keep in tightly closed containers.

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
7-2-A2, Hetero Corporate,
Industrial Estates, Sanath Nagar,
Hyderabad – 500 018, Telangana, INDIA
Tel: 0091-40-23704923/24/25

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA498

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE