

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[HA498 trade name]*

Emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

2. Statement of active substance

Each tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate

3. List of excipients

Contains lactose monohydrate

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

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 sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

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

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

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

12. WHO Reference Number (Prequalification Programme)

HA498

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