LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HA620 trade name]* Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablet

Lamivudine/tenofovir disoproxil fumarate

2. Statement of active substance

Each film-coated tablet contains 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate

3. List of excipients

Each film-coated tablet contains 153 mg of lactose monohydrate

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets

30 tablets

100 tablets

5. Method and route of administration

Oral use.

Do not chew.

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 30ºC.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

11. Name and address of the supplier

Micro Labs Limited

31, Race Course Road

Bengaluru- 560001, Karnataka, India Tel: +91-80-2237 0451/57

Fax: +91-80-2237 0463

12. WHO Reference Number (Prequalification Programme)

HA620

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle label

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[HA620 trade name][†] Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg tablet

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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.

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