

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA523 trade name] *Lamivudine 10 mg/mL Oral Solution

Lamivudine

2. Statement of active substance

Each mL of oral solution contains 10 mg of lamivudine.

3. List of excipients

Contains sucrose, methyl paraben, propyl paraben and propyleneglycol.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

240 mL oral solution.

100 mL oral solution.

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}

9. Special storage conditions

Do not store above 30°C.

Discard the product 30 days after initial opening.

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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road

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

Andheri (East)
Mumbai – 400 059, India.
Tel: +91-22-66762800
Fax: +91 -22-28216599

12. WHO Reference Number (Prequalification Programme)

HA523

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