

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

HDPE bottle label

1. NAME OF THE MEDICINAL PRODUCT

Lamivudine 10 mg/ml Oral Solution *

2. STATEMENT OF ACTIVE SUBSTANCE

Each ml of oral solution contains 10 mg of lamivudine

3. LIST OF EXCIPIENTS

Contains sucrose, methyl paraben and propyl paraben. 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 out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

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
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> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE