

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label (blister and HDPE bottle)

1. NAME OF THE MEDICINAL PRODUCT

[HA644 trade name]*

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains lamivudine 150mg

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

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

Do not store above 30°C. Protect from light.

Store capsules in blisters in the provided carton.

* 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

Micro Labs Limited
31 Race Course Road
Bangalore – 560001
Karnataka
India
Tel: +91-80-2237 0451 to 2237 0457
Fax: +91-80-2237 046

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA644

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

14. (Advice on) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

[HA644 trade name]

2. NAME OF THE SUPPLIER

Micro Labs Ltd

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}