

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

[HA629 trade name]*

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains lamivudine 150 mg, nevirapine 200 mg and zidovudine 300 mg

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated 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

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

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Keep the bottle tightly closed.

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

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA629

13. MANUFACTURER'S BATCH NUMBER

<BN> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

Carton (PVC/PVDC-ALU blister)

1. NAME OF THE MEDICINAL PRODUCT

[HA629 trade name]

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains lamivudine 150 mg, nevirapine 200 mg and zidovudine 300 mg

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets

6 x 10 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. Store tablets in the blisters in the provided carton..

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

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA629

13. MANUFACTURER'S BATCH NUMBER

<BN> {number}

14. 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

[HA629 trade name]

2. NAME OF THE SUPPLIER

Micro Labs Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

BN {number}