LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton label

1. NAME OF THE MEDICINAL PRODUCT

[HA490 trade name]*
Lamivudine and zidovudine

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 150 mg lamivudine, 300 mg zidovudine.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

60 film-coated tablets
Scored tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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 reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store below 30°C
Protect from light.

*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

Universal Corporation Limited
Club Road Plot Number 13777
P.O. Box 1748 – 00902
Kikuyu
Kenya
Tel: + 254-66-31459/60
Fax: + 254-66-31461
Email: info@ucl.co.ke

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA490

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

Dosage: As directed by the physician.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle label

1. NAME OF THE MEDICINAL PRODUCT

[HA490 trade name][†]
Lamivudine and zidovudine

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 150 mg lamivudine, 300 mg zidovudine.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

60 film-coated tablets
Scored tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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 reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

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

Do not store above 30°C and protect from light. The bottle should be kept 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

Universal Corporation Limited
Club Road Plot Number 13777
P.O. Box 1748 – 00902
Kikuyu
Kenya
Tel: + 254-66-31459/60
Fax: + 254-66-31461
Email: info@ucl.co.ke

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA490

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

Dosage: As directed by the physician.