

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton label

1. NAME OF THE MEDICINAL PRODUCT

[HA521 trade name] *

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

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}

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

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Tablets should be kept in a tightly closed container, protected from light.

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

Hetero Labs Limited
Unit III, #22-110, I.D.A., Jeedimetla
Qutubullapur Municipality
Hyderabad, Rangareddy Dist – 500 055
Andhra Pradesh
INDIA
Contact: – Mr. A. Vamsikanth, Manager-RA
Phone:+91-40-23704923/24/25
Email: ma Vamsikanth.A@heterodrugs.com

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA521

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle label

1. NAME OF THE MEDICINAL PRODUCT

[HA521 trade name][†]

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

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}

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

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Tablets should be kept in a tightly closed container, protected from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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