# LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING**

**Outer carton and bottle label/HDPE**

## 1. NAME OF THE MEDICINAL PRODUCT

Lamivudine and Zidovudine Tablets 150 + 300 mg*

## 2. STATEMENT OF ACTIVE SUBSTANCE

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

## 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}

* 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.

## 9. SPECIAL STORAGE CONDITIONS

Do not store above 30˚C. Store in the original package in order to protect from moisture

## 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

Sun Pharmaceutical Industries Limited
Paonta Sahib
District Sirmour
Himachal Pradesh – 173025
INDIA.
Fax : (00-91-1704) 223492
Telephone: +91 1704 662201

## 12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA286

## 13. MANUFACTURER'S BATCH NUMBER

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

## 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

## 15. INSTRUCTIONS ON USE

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING**

**Carton/Blisters (Alu-PA/PVC and Alu/PVC/PVdC)**

**1. NAME OF THE MEDICINAL PRODUCT**

Lamivudine and Zidovudine Tablets 150 + 300 mg

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each film-coated tablet contains 150 mg lamivudine and 300 mg zidovudine

**3. LIST OF EXCIPIENTS**

See patient information leaflet for further information

**4. PHARMACEUTICAL FORM AND CONTENTS**

10x6 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 in the original package in order to protect from moisture

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

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## 13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <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**

Lamivudine and Zidovudine Tablets 150 + 300 mg

**2. NAME OF THE SUPPLIER**

Sun Pharmaceutical Industries Limited

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

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