

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle label

1. Name of the medicinal product

[HA537 trade name]*

Zidovudine 60 mg Tablets

2. Statement of active substance

Each film-coated tablet contains 60 mg zidovudine.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

60 Tablets

100 Tablets

500 Tablets

1000 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 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 high humidity

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

11. Name and address of the supplier

Supplied by:
Micro Labs Limited
31, Race Course Road
Bangalore - 560001, Karnataka
India.

Manufactured by:
Micro Labs Limited
Plot No: S-155 to S-159 & N1
Phase III & Phase IV
Verna Industrial Estate, Verna
Goa- 403722
India

12. WHO Reference Number (Prequalification Programme)

HA537

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister pack carton

1. Name of the medicinal product

[HA537 trade name]

Zidovudine 60 mg Tablets

2. Statement of active substance

Each film-coated tablet contains 60 mg zidovudine.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

10 x 10

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 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 high humidity. Store tablets in 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

Supplied by:

Micro Labs Limited

31, Race Course Road

Bangalore - 560001, Karnataka

India.

Manufactured by:
Micro Labs Limited
Plot No: S-155 to S-159 & N1
Phase III & Phase IV
Verna Industrial Estate, Verna
Goa- 403722
India

12. WHO Reference Number (Prequalification Programme)

HA537

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP
PVC/PVDC–Aluminium Blisters**

1. Name of the medicinal product

[HA537 trade name]

Zidovudine 60 mg Tablets

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other