

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton label

1. Name of the medicinal product

[HA486 trade name]*

2. Statement of active substance

Each 5 mL of oral solution contains 50 mg of zidovudine

3. List of excipients

Contains sucrose. See patient information leaflet for further information

4. Pharmaceutical form and contents

240 mL oral solution

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.

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 Ltd
7-2-A2 Hetero Corporate

Industrial Estates
Sanath Nagar
Hyderabad 500 018
Telangana
INDIA
Tel: + 91 40 23704923
Fax: + 91 40 23704926
Email: contact@heterodrugs.com

12. WHO Reference Number (Prequalification Programme)

HA486

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

Bottle label

1. Name of the medicinal product

[HA486 trade name]*

2. Statement of active substance

Each 5 mL of oral solution contains 50 mg of zidovudine

3. List of excipients

Contains sucrose. See patient information leaflet for further information

4. Pharmaceutical form and contents

240 mL oral solution

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

11. Name and address of the supplier

Hetero Labs Ltd
7-2-A2 Hetero Corporate

Industrial Estates
Sanath Nagar
Hyderabad 500 018
Telangana
INDIA
Tel: + 91 40 23704923
Fax: + 91 40 23704926
Email: contact@heterodrugs.com

12. WHO Reference Number (Prequalification Programme)

HA486

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