

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic (HDPE) bottle

1. Name of the medicinal product

[HA486 trade name]* Zidovudine 50 mg/5 mL oral solution
Zidovudine

2. Statement of active substance

Each 5 mL of oral solution contains 50 mg 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 this medicine 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.

Discard the solution one month after first opening.

Date of opening: DD/MM/YY

* 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

Hetero Labs Ltd
7-2-A2 Hetero Corporate
Industrial Estates
Sanath Nagar
Hyderabad 500 018
Telangana
India

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