

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle label

1. Name of the medicinal product

[HA526 trade name]*

Zidovudine 50 mg/5 mL Oral Solution

2. Statement of active substance

Each 5 mL of oral solution contains 50 mg of zidovudine.

3. List of excipients

Contains sucrose and sodium benzoate

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Oral solution

240 mL

100 mL

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

Store in a tightly closed bottle. Do not store above 30°C.

Discard the solution 28 days after first opening.

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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059, INDIA.
Tel: +91-22-66762800
Fax: +91 -22-28216599
Email: sjadhav@macleodspharma.com

12. WHO Reference Number (Prequalification Programme)

HA526

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

Carton label

1. Name of the medicinal product

[HA526 trade name]

Zidovudine 50 mg/5 mL Oral Solution

2. Statement of active substance

Each 5 mL of oral solution contains 50 mg of zidovudine.

3. List of excipients

Contains sucrose and sodium benzoate

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Oral solution

240 mL

100 mL

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

Store in a tightly closed bottle. Do not store above 30°C.

Discard the solution 28 days after first opening.

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

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<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use