

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[HA483 trade name]* Zidovudine Tablets USP 300 mg
Zidovudine

2. Statement of active substance

Each film-coated tablet contains 300 mg zidovudine

3. List of excipients

4. Pharmaceutical form and contents

100 (10x10) film-coated 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 and sight 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

Micro Labs Ltd
31, Race Course Road
Bengaluru - 560001
Karnataka
India
Tel: +91-80-22370451 to 22370457
Fax: +91-80-22370463

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

12. WHO Reference Number (Prequalification Programme)

HA483

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

PVDC/PVC – Aluminium blister

1. Name of the medicinal product

[HA483 trade name] Zidovudine 300 mg Tablets USP
Zidovudine

2. Name of the supplier

Micro Labs Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton label

1. Name of the medicinal product

[HA483 trade name][†] Zidovudine Tablets USP 300 mg
Zidovudine

2. Statement of active substance

Each film-coated tablet contains 300 mg zidovudine

3. List of excipients

4. Pharmaceutical form and contents

30 film-coated tablets
60 film-coated tablets
90 film-coated 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 and sight 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

Micro Labs Ltd
31, Race Course Road
Bengaluru - 560001
Karnataka

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

India

Tel: +91-80-22370451 to 22370457

Fax: +91-80-22370463

12. WHO Reference Number (Prequalification Programme)

HA483

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

[HA483 trade name][‡] Zidovudine Tablets USP 300 mg
Zidovudine

2. Statement of active substance

Each film-coated tablet contains 300 mg zidovudine

3. List of excipients

4. Pharmaceutical form and contents

30 film-coated tablets
60 film-coated tablets
90 film-coated 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 and sight 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

Micro Labs Ltd
31, Race Course Road
Bengaluru -560001
Karnataka

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

India

Tel: +91-80-22370451 to 22370457

Fax: +91-80-22370463

12. WHO Reference Number (Prequalification Programme)

HA483

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