

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA555 trade name]* Lamivudine/zidovudine 30 mg/60 mg tablets
Lamivudine/zidovudine

2. Statement of active substance

Each film-coated tablet contains 30 mg lamivudine and 60 mg zidovudine.

3. List of excipients

4. Pharmaceutical form and contents

60 film-coated tablets

100 film-coated tablets

1000 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 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

Store at or below 30°C. Protect from light.

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 Limited
#31, Race Course Road
Bengaluru– 560001
Karnataka,
India.

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

12. WHO Reference Number (Prequalification Programme)

HA555

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 carton

1. Name of the medicinal product

[HA555 trade name][†] Lamivudine/zidovudine 30 mg/60 mg tablets
Lamivudine/zidovudine

2. Statement of active substance

Each film-coated tablet contains 30 mg lamivudine and 60 mg zidovudine.

3. List of excipients

4. Pharmaceutical form and contents

60 film-coated tablets (6 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 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

Store at or below 30°C. Protect from light. 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

Micro Labs Limited
#31, Race Course Road
Bengaluru– 560001
Karnataka,
India.

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

12. WHO Reference Number (Prequalification Programme)

HA555

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

(PVC/PVDC)-Aluminium blisters

1. Name of the medicinal product

[HA555 trade name] Lamivudine/zidovudine 30 mg/60 mg tablets

Lamivudine/zidovudine

2. Name of the supplier

Micro Labs Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot> number

5. Other