

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic (HDPE) bottle

1. Name of the medicinal product

[HA459 trade name] * Lamivudine/Zidovudine 150 mg/300 mg tablets
Lamivudine/Zidovudine

2. Statement of active substance

Each tablet contains 150 mg lamivudine and 300 mg zidovudine

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet
60 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

Do not store above 30°C. Store in a dry place, protected from light.

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)
400 059 Mumbai
India

12. WHO Reference Number (Prequalification Programme)

HA459

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

[HA459 trade name][†] Lamivudine/Zidovudine 150 mg/300 mg tablets
Lamivudine/Zidovudine

2. Statement of active substance

Each tablet contains 150 mg lamivudine and 300 mg zidovudine

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet
6× 10 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

Do not store above 30°C. Store in a dry place, protected from light.

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)
400 059 Mumbai
India

12. WHO Reference Number (Prequalification Programme)

HA459

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

Blister

1. Name of the medicinal product

[HA459 trade name] Lamivudine/Zidovudine 150 mg/300 mg tablets
Lamivudine/Zidovudine

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other