LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HA572 trade name][*] Lamivudine/zidovudine 30 mg/60 mg dispersible tablets

Lamivudine and zidovudine

2. Statement of active substance

Each dispersible tablet contains 30 mg lamivudine and 60 mg zidovudine.

3. List of excipients

Contains aspartame

See patient information leaflet for further information.

4. Pharmaceutical form and contents

60 dispersible 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 the original package.

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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad – 500096,
Telangana, India
Tel No: +91 40 39258109
Email: ProductSafety@viatris.com

12. WHO Reference Number (Prequalification Programme)

HA572

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 IMMEDIATE PACKAGING

Bottle label

1. Name of the medicinal product

[HA572 trade name][†] Lamivudine/zidovudine 30 mg/60 mg dispersible tablets

Lamivudine and zidovudine

2. Statement of active substance

Each dispersible tablet contains 30 mg lamivudine and 60 mg zidovudine.

3. List of excipients

Contains aspartame

See patient information leaflet for further information.

4. Pharmaceutical form and contents

60 dispersible 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 the original package.

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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad – 500096,
Telangana, India
Email: ProductSafety@viatris.com

12. WHO Reference Number (Prequalification Programme)

HA572

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