Lamivudine/tenofovir disoproxil
fumarate 300mg/300mg tablets
(Mylan Laboratories Ltd), HA414

WHOPAR Part 5

September 2024

LABELLING

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fumarate 300mg/300mg tablets
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PARTICULARS TO APPEAR ON THE OUTER PACKAGING

White HDPE bottle (30's and 100's) or

Blue HDPE bottle (30's)

1. Name of the medicinal product

[HA414 trade name][*] Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg film coated tablets

Lamivudine and Tenofovir Disoproxil Fumarate

2. Statement of active substance

Each film-coated tablet contains 300 mg lamivudine and 300mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

3. List of excipients

Contains lactose. See patient information leaflet for further information

4. Pharmaceutical form and contents

30 film-coated tablets
100 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

None

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Store in the original container. Protect from light

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

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11. Name and address of the supplier

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad –500096,
Telangana,
India

12. WHO Reference Number (Prequalification Programme)

HA414

13. Manufacturer's batch number

Batch {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use