

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle carton label

1. Name of the medicinal product

[HA521 trade name]*

Lamivudine/zidovudine 150 mg/300 mg tablets

2. Statement of active substance

Each film-coated tablet contains 150 mg lamivudine and 300 mg zidovudine.

3. List of excipients

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

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. Tablets should be kept in a tightly closed container, protected 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

Hetero Labs Limited,

Hetero Corporate, 7-2-A2,

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

Industrial Estates,
Sanath Nagar,
Hyderabad – 500018,
Telangana, India.
Tel: +91-40-23704923

12. WHO Reference Number (Prequalification Programme)

HA521

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

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