

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA635 trade name]* Abacavir (as sulfate) / Lamivudine 600 mg / 300 mg tablets

2. Statement of active substance

Each tablet contains 600 mg abacavir (as sulfate) and 300 mg lamivudine

3. List of excipients

The tablets also contain FD&C Yellow #6/Sunset Yellow FCF Aluminium Lake.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

28 tablets

30 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 container.

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

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

12. WHO Reference Number (Prequalification Programme)

HA635

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

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

15. Instructions on use