

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA698 trade name]¹ Abacavir sulfate/lamivudine 600mg/300mg tablets
Abacavir sulfate/lamivudine

2. Statement of active substance

Each film coated tablet contains 600 mg of abacavir sulfate and 300 mg lamivudine.

3. List of excipients

Contains FD&C Yellow #6/Sunset Yellow FCF Aluminium Lake.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

30 film-coated tablets.

90 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 out of 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. Avoid excursions above 30°C.

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

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

11. Name and address of the supplier

Sun Pharmaceutical Industries Limited.
Sun House, 201 B/1
Western Express Highway
Goregaon (East)
Mumbai - 400063, India.
Email:
Complaintdesk.Tandalja@sunpharma.com
pharmacovigilance.africasme@sunpharma.com

12. WHO Reference Number (Prequalification Programme)

HA698

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use