

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle carton

1. Name of the medicinal product

[HA662 trade name]* Abacavir (as sulfate)/lamivudine 120 mg/60 mg dispersible tablets
Abacavir (as sulfate)/lamivudine

2. Statement of active substance

Each uncoated dispersible tablet contains Abacavir Sulfate USP equivalent to Abacavir 120 mg and Lamivudine USP 60 mg

3. List of excipients

Contains aspartame, see patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

1 x 60 tablets

1 x 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 out of the reach of children.

7. Other special warning(s), if necessary

Detach Alert Card enclosed in the pack, it contains important safety information

WARNING! In case of any symptoms suggesting hypersensitivity reactions, contact your healthcare provider IMMEDIATELY.

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C.

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

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

Cipla Limited Cipla House,
Peninsula Business Park
Ganpatrao Kadam Marg, Lower Parel Mumbai -400013,
India
Tel.: 91 22 4191 6000
Fax: 91 22 4191 6120

12. WHO Reference Number (Prequalification Programme)

HA662

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

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