

LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA674 trade name]* Abacavir (as sulphate) 60 mg dispersible tablets

Abacavir (as sulphate)

2. Statement of active substance

Each dispersible tablet contains 60 mg of abacavir (as sulfate)

3. List of excipients

Contains aspartame

See patient information leaflet for further information.

4. Pharmaceutical form and contents

60 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 and sight 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 health care provider IMMEDIATELY.

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Protect from light and moisture.

Keep the container tightly closed.

* 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

Micro Labs Limited
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Bangalore - 560001, Karnataka
India
Tel: +91-80-2237 0451 to 2237 0457
Fax: +91-80-2237 0463
Email: exp@microlabs.in

12. WHO Reference Number (Prequalification Programme)

HA674

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