

LABELLING

**PARTICULARS TO APPEAR ON THE IMMEDIATE AND OUTER
PACKAGING**

HDPE bottle/Carton

1. Name of the medicinal product

[HA518 trade name]* abacavir (as sulfate)/lamivudine 60mg/30mg dispersible tablets

Abacavir (as sulfate)/lamivudine

2. Statement of active substance

Each film-coated tablet contains 60 mg abacavir (as sulfate) and 30mg lamivudine.

3. List of excipients

Contains aspartame.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

60 dispersible tablets

120 dispersible 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}

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

9. Special storage conditions

Do not store above 30°C.

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, Maharashtra 400013
India
Tel No.: 91222482600
Fax No.: 912224826120

12. WHO Reference Number (Prequalification Programme)

HA518

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