LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE AND OUTER PACKAGING

HDPE bottle/Carton

1. Name of the medicinal product

[HA371 trade name]* abacavir (as sulfate) 300mg tablets

Abacavir (as sulfate)

2. Statement of active substance

Each film-coated tablet contains 300 mg abacavir (as sulfate).

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

60 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 the reach and sight 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.

* 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, Maharashtra 400013 India

Tel No.: 91222482600 Fax No.: 912224826120

12. WHO Reference Number (Prequalification Programme)

HA371

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