LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
HDPE bottle

1. Name of the medicinal product

[HA779 trade name][*] Abacavir (as sulfate)/ dolutegravir (as sodium)/ lamivudine 60 mg/5 mg/30 mg film-coated dispersible tablets

Abacavir (as sulfate)/ dolutegravir (as sodium)/ lamivudine

2. Statement of active substance

Each tablet contains 60 mg abacavir (as sulfate), 5 mg dolutegravir (as sodium) and 30 mg lamivudine

3. List of excipients

Each tablet contains aspartame.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

30 tablets

90 tablets

180 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 this medicine 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. Store in the original container.

[*] 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

12. WHO Reference Number (Prequalification Programme)

HA779

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