

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA790 trade name]* Abacavir (as sulfate)/dolutegravir (as sodium)/lamivudine 60 mg/5 mg dispersible tablets

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

2. Statement of active substance

Each tablet contains 70.27 mg abacavir sulfate, equivalent to 60 mg abacavir, 5.26 mg dolutegravir sodium equivalent to 5 mg dolutegravir and 30 mg lamivudine.

3. List of excipients

Contains mannitol

4. Pharmaceutical form and contents

Dispersible tablets

1 x 180 tablets

1 x 120 tablets

1 x 90 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 this medicine out of the sight and reach 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 original package to protect from moisture. Keep the bottle tightly closed. Do not remove desiccant.

* 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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East)
Mumbai – 400055
India

12. WHO Reference Number (Prequalification Programme)

HA790

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