LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA650 trade name]* Lopinavir 100 mg and Ritonavir 25 mg tablets Lopinavir and ritonavir

2. Statement of active substance

Each tablet contains 100 mg lopinavir and 25 mg ritonavir

3. List of excipients

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

120 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
- 7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

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

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

Hetero Labs Limited

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

Hetero Corporate, 7-2-A2 Industrial Estates Sanath Nagar Hyderabad – 500018 Telangana, India

12. WHO Reference Number (Prequalification Programme)

HA650

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