

## **LABELLING**

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

**HDPE bottle**

**1. NAME OF THE MEDICINAL PRODUCT**

[HA650 trade name]\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each tablet contains 100 mg lopinavir and 25 mg ritonavir.

**3. LIST OF EXCIPIENTS**

See 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**

Keep out of the reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

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

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  
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> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**