LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HA760 trade name]*

Lopinavir/ritonavir 100 mg/25 mg tablets

2. Statement of active substance

Each film coated tablet contains lopinavir 100 mg and ritonavir 25 mg

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

60 tablets

120 tablets

5. Method and route of administration

Oral use.

Do not chew.

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.

Discard the product 30 days after initial opening.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Page 2 of 5

11. Name and address of the supplier

Micro Labs Limited

#31, Race Course Road,

Bangalore - 560001, Karnataka, India

12. WHO Reference Number (Prequalification Programme)

HA760

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle label

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[HA760 trade name][†]

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2. Statement of active substance

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3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

60 tablets

120 tablets

5. Method and route of administration

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6. Special warning that the medicinal product must be stored out of the reach and sight of children

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7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C.

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