LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[HA761 trade name]* Lopinavir/ritonavir 200mg/50mg tablets Lopinavir and ritonavir

2. Statement of active substance

Each film coated tablet contains 200 mg lopinavir and 50 mg ritonavir.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

60 film-coated tablets

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 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. Tel.: +91-80-2237 0451 to 2237 0457

Fax.: +91-80-2237 0463

12. WHO Reference Number (Prequalification Programme)

HA761

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON HDPE BOTTLE

HDPE bottle

1. Name of the medicinal product

[HA761 trade name][†] Lopinavir/ritonavir 200mg/50mg tablets Lopinavir and ritonavir

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8. Expiry date

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