

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[HA573 trade name]*Lopinavir/ritonavir 100mg/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 patient information leaflet for further information.

4. Pharmaceutical form and contents

60 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

Store below 30°C, in dry place protected from light.

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.

11. Name and address of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059, India
Tel: +91-22-66762800
Fax:+91 -22-29256599

12. WHO Reference Number (Prequalification Programme)

HA573

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 THE IMMEDIATE PACKAGING

HDPE Bottle label

1. Name of the medicinal product

[HA573 trade name][†]Lopinavir/ritonavir 100mg/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 patient information leaflet for further information.

4. Pharmaceutical form and contents

60 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

Store below 30°C, in dry place protected from light.

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.

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<Batch>{number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use