

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[HA679 trade name]* Lopinavir/ritonavir 40 mg/10 mg granules for oral suspension
Lopinavir and ritonavir

2. Statement of active substance

Each sachet contains 40 mg lopinavir and 10 mg ritonavir.

3. List of excipients

Contains mannitol

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Granules for oral suspension

120 sachets

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 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. Store in the original container.

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

Mylan Laboratories Limited
Plot No. 564/A/22, Road No. 92, Jubilee Hills
Hyderabad-500096
Telangana
India

12. WHO Reference Number (Prequalification Programme)

HA697

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

MINIMUM PARTICULARS TO APPEAR ON SACHETS

Sachet

1. Name of the medicinal product

[HA697 trade name]

Lopinavir/ritonavir 40 mg/10 mg granules for oral suspension

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other