

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic (HDPE) bottle

1. Name of the medicinal product

[HA492 trade name]* Lopinavir/ritonavir 200 mg/50 mg tablets
Lopinavir / Ritonavir

2. Statement of active substance

Each tablet contains 200 mg lopinavir and 50 mg ritonavir.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

60 tablets

120 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. Store in the original container. Store tablets packaged in blisters in the provided carton.

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 - 500 018
Telangana
India

12. WHO Reference Number (Prequalification Programme)

HA492

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

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

Blister/strip pack carton

- 1. Name of the medicinal product**
[HA492 trade name] Lopinavir/ritonavir 200 mg/50 mg tablets
Lopinavir / Ritonavir
- 2. Statement of active substance**
Each tablet contains 200 mg lopinavir and 50 mg ritonavir.
- 3. List of excipients**
- 4. Pharmaceutical form and contents**
Film-coated tablets
10 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. Store in the original container. Store tablets packaged in blisters in the provided carton.
- 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 - 500 018, Telangana
India
- 12. WHO Reference Number (Prequalification Programme)**
HA492
- 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 BLISTERS OR STRIP

PVC/PVdC-Alu blister or Alu/Alu strip pack

- 1. Name of the medicinal product**
[HA492 trade name] Lopinavir/ritonavir 200 mg/50 mg tablets
Lopinavir/ritonavir
- 2. Name of the supplier**
Hetero Labs Limited
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Manufacturer's batch number**
<Batch> <Lot>{number}
- 5. Other**