

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[CV012 trade name]*

Nirmatrelvir 150 mg tablets + Ritonavir 100 mg tablets USP Co pack

2. Statement of active substance

Nirmatrelvir 150mg tablets

Each film coated tablet contains 150 mg nirmatrelvir

Ritonavir 100 mg USP tablets

Each film coated tablet contains 100 mg ritonavir

3. List of excipients

Nirmatrelvir 150mg tablets

Each film coated tablet contains lactose monohydrate and sodium.

Ritonavir 100 mg tablets USP

Each film coated tablet contains sodium.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

Alu-Alu blister pack. Each blister card contains 4 Nirmatrelvir 150 mg tablets and 2 Ritonavir 100 mg tablets. Such 5 blister cards are packed in a carton.

Pack size: 5 x 6's 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 reach and sight of children.

7. Other special warning(s), if necessary

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

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C.

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
Telangana, 500 018
India.
Tel : +91 40 23704923/ 24/25
Fax : +91 40 23714250 / 2370 4926
Email: contact@heterodrugs.com

12. WHO Reference Number (Prequalification Programme)

CV012

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

Alu-Alu blisters

1. Name of the medicinal product

[CV012 trade name][†]

Nirmatrelvir 150 mg tablets + Ritonavir 100 mg tablets USP Co pack

2. Name of the supplier

Hetero Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

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