LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[CV024 trade name][*] Nirmatrelvir+Ritonavir 150mg+100mg film coated tablets (co-packaged)

Nirmatrelvir+Ritonavir

2. Statement of active substance

Nirmatrelvir 150 mg film coated tablets

Each film coated tablet contains 150 mg nirmatrelvir.

Ritonavir 100 mg film coated tablets

Each film coated tablet contains 100 mg ritonavir.

3. List of excipients

Nirmatrelvir 150 mg film coated tablets

Each film coated tablet contains lactose monohydrate.

Ritonavir 100 mg film coated tablets

Each film-coated tablet contains 87.76 mg of sodium.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film coated Tablets

30’s (20 nirmatrelvir tablets + 10 ritonavir tablets).

5. Method and route of administration

Oral use.

Do not chew.

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}

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

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

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)

CV024

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 blister

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Nirmatrelvir+Ritonavir

2. Name of the supplier

Mylan Laboratories Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other