

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Outer carton

### **1. Name of the medicinal product**

[CV024 trade name]\* Nirmatrelvir+Ritonavir 150mg+100mg 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**

Tablets

30 film-coated tablets (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}

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\* 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 original the 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

**1. Name of the medicinal product**

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

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**