

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[CV018 trade name]*

Nirmatrelvir 150 mg tablets + Ritonavir 100 mg tablets Co pack

2. Statement of active substance

Nirmatrelvir 150 mg tablets

Each film coated tablet contains 150 mg nirmatrelvir.

Ritonavir 100 mg tablets

Each film coated tablet contains 100 mg ritonavir.

3. List of excipients

Nirmatrelvir 150 mg tablets

Each film coated tablet contains lactose monohydrate, sodium, FD&C yellow #5/tartrazine aluminium lake and FD&C yellow #6/sunset yellow FCF aluminium lake.

Ritonavir 100 mg tablets

Each film coated tablet contains sodium.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

Opaque silver plastic (Polyamide/Alu/PVC) on aluminium foil blister cards each containing 4 Nirmatrelvir 150 mg film-coated tablets and 2 Ritonavir 100 mg film-coated tablets. Such 5 blister cards are packed in a carton.

Available in cartons of 5×6 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

* 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. Store tablets in the 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

Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd
333 Jiangnan Road,
Hengdian, Dongyang,
Zhejiang province,
P.R.China

12. WHO Reference Number (Prequalification Programme)

CV018

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

Polyamide/Alu/PVC-Alu blister

1. Name of the medicinal product

[CV018 trade name]

Nirmatrelvir 150 mg tablets + Ritonavir 100 mg tablets Co pack

2. Name of the supplier

Zhejiang Apelo Kangyu Pharmaceutical Co. Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other