Nirmatrelvir 150 mg + ritonavir 100 mg tablets (Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd), CV020

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[CV020 trade name]* Nirmatrelvir 150 mg tablets + ritonavir 100 mg tablets Co pack Nirmatrelvir and ritonavir

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 185 mg of lactose monohydrate See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablets

[CV020 trade name] are packed in a blister card (polyamide/Alu/PVC-Alu) each containing 4 nirmatrelvir tablets and 2 ritonavir tablets. 5 of such blister cards are packed in a carton.

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

9. Special storage conditions

Do not store above 30°C.

^{*} Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Page 2 of 4

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

Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd (Fosun Pharma) Room 350, No. 25 Kangshi Road, Kangqiao Town, Pudong New District (Kangqiao), Shanghai, 201315 People's Republic of China

12. WHO Reference Number (Prequalification Programme)

CV020

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

Blister

1. Name of the medicinal product

[CV020 trade name][†] Nirmatrelvir 150 mg tablets + ritonavir 100 mg tablets Co pack Nirmatrelvir and ritonavir

2. Name of the supplier

Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd (Fosun Pharma)

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

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