

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[CV008 trade name]* Molnupiravir 200 mg hard capsule

Molnupiravir

2. Statement of active substance

Each capsule contains 200 mg molnupiravir

3. List of excipients

4. Pharmaceutical form and contents

Hard capsules

40 capsules

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 sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Store below 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

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

India

12. WHO Reference Number (Prequalification Programme)

CV008

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[CV008 trade name][†] Molnupiravir 200 mg hard capsule

Molnupiravir

2. Statement of active substance

Each capsule contains 200 mg molnupiravir

3. List of excipients

4. Pharmaceutical form and contents

Hard capsules

4 x 10 capsules

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 sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Store below 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
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India

12. WHO Reference Number (Prequalification Programme)

CV008

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Alu-Alu blister

1. Name of the medicinal product

[CV008 trade name] Molnupiravir 200 mg hard capsules

Molnupiravir

2. Name of the supplier

Hetero Labs Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> {number}

5. Other