

Module 1- Administrative and Prescribing Information

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

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- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

What is in this leaflet

- 1. What Molnupiravir Capsules 200mg is and what it is used for
- 2. What you need to know before you take Molnupiravir Capsules 200mg
- 3. How to take Molnupiravir Capsules 200mg
- 4. Possible side effects
- 5. How to store Molnupiravir Capsules 200mg
- 6. Contents of the pack and other information

1. WHAT MOLNUPIRAVIR CAPSULES 200MG IS AND WHAT IT IS USED FOR

Molnupiravir is indicated for the treatment of mild to moderate COVID-19 infection

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOLNUPIRAVIR CAPSULES 200MG

Data not available

3. HOW TO TAKE MOLNUPIRAVIR CAPSULES 200MG

Dosage : Molnupiravir administered orally in capsule form every 12 hours for 5 days.



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Method of administration : To be taken orally, swallowed as whole.

4. POSSIBLE SIDE EFFECTS

Hypersensitivity to Molnupiravir or any of its components

Other effects:

The following are the adverse events reported during the clinical trials: Headache, diarrhoea, catheter site pain, nausea, rhinorrhoea, back pain, feeling hot, oropharyngeal pain, somnolence, rash and pain in extremity.

5. HOW TO STORE MOLNUPIRAVIR CAPSULES 200MG

Store below 30°C and protect from moisture

6. CONTENTS OF THE PACK AND OTHER INFORMATION

4 × 10's Alu-Alu Blister Pack:

Forming Foil: Cold Form Foil 148mm (60 microns PVC/45 microns aluminium foil /25 microns OPA)

Lidding Foil: 0.025×148 mm, plain aluminium foil (Hard tempered) with 7GSM HSL Coating on bright Side.

40's HDPE Container;

Container: High Density Polyethylene Container 100cc with 38 mm Neck (Heavy weight **Closure:** 38mm CT plastic caps with pulp liner

Silica gel: Canister silica gel 1 gram.

List of excipients

Microcrystalline Cellulose, Hydroxypropyl cellulose, Croscarmellose sodium, Purified

water, Magnesium stearate, Hard Cellulose Capsule Shells.

Hard Cellulose Capsule Shell ingredients are: Hypromellose, Purified water, Carrageenan

and Potassium Chloride.

Hetero Labs Limited. India



7. Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder

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