



1.7 Product information:

1.7.1 Summary of product characteristics (SmPC)

The summary of product characteristics of Molnupiravir Capsules 200mg is given in the following.

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the finished pharmaceutical product

INN Name: Molnupiravir Capsules

Trade Name: MOVFOR

Strength: 200 mg

Pharmaceutical form: Capsules

2. Qualitative and quantitative composition

Each Molnupiravir 200 mg capsule contains Molnupiravir 200 mg

3. Pharmaceutical form

Dosage form: Capsule

Description: Green/ Green Size “0” hard cellulose Capsules filled with white to off white powder.

4. Clinical particulars

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Dosage

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

Method of administration



To be taken orally, swallowed as whole.

4.3 Contraindications

Hypersensitivity to Molnupiravir or any of its components

4.4 Special warnings and precautions for use

Data not available

4.5 Interaction with other medicinal products and other forms of interaction

Data not available

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no studies conducted in pregnant women or animals. Data not available

Lactation

There are no studies conducted in pregnant women or animals. Data not available.

4.7 Effects on ability to drive and use machines

Data not available

4.8 Undesirable 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.

4.9 Overdose

Data not available

5. Pharmacological properties

5.1 Pharmacodynamic properties



Pharmacotherapeutic group: Anti-viral drug

Mechanism of action

Molnupiravir is a prodrug of synthetic nucleoside derivative N4-hydroxycytidine, and exerts its antiviral action through introduction of copying errors during viral RNA replication. The antiviral activity of Molnupiravir was demonstrated for alphaviruses, pneumoviruses and orthomyxoviruses, and confirmed to equally apply to Betacoronaviruses. Activity has also been demonstrated against coronaviruses including SARS, MERS and SARS-CoV-2.

5.2 Pharmacokinetics properties

In Single and multiple dose studies, Molnupiravir appeared rapidly in plasma, with a median time of maximum observed concentration of 1.00 to 1.75 hours, and declined with a geometric half-life of approximately 1 hour, with a slower elimination phase apparent following multiple doses or higher single doses (7.1 hours at the highest dose tested). Mean maximum observed concentration and area under the concentration versus time curve increased in a dose-proportional manner, and there was no accumulation following multiple doses.

Food Effect:

In fed state, there was a decrease in the rate of absorption, but no decrease in overall exposure.

5.3 Preclinical safety data

Animal Toxicology or Pharmacology

Data not available

6. Pharmaceutical particulars

6.1 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.



6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C and protect from moisture

6.5 Nature and contents of container

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 × 148mm, 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.

Space Filler: Purified Cotton 9 gram/yard

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorisation Holder and Manufacturing Site Addresses

7.1 Marketing Authorisation Holder

Name : Hetero Labs Limited

Business Address : 7-2-A2, Hetero Corporate,



Industrial Estates, Sanath Nagar,
Hyderabad-500 018
Telangana.

Country : INDIA
Telephone : 0091-040-23704923/24

Manufactured by:

Hetero Labs Limited,
UNIT-V, TSIIC Formulation SEZ,
Polepally Village, Jadcherla Mandal,
Mahaboobnagar Dist., Telangana, INDIA.
Tel Ph.: + 91 08542-238400
Telefax: +91 08542 238404

8. Registration Number

Not Applicable

9. Category for Distribution

Prescription only medicine

10. Date of publication of this package Insert.