WARNING: To be sold by retail on prescription of Medical specialist only.

℞ Molnupiravir Capsules 200 mg

MOLNATRIS™

1. NAME OF THE MEDICINAL PRODUCT

Molnupiravir Capsules 200 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Capsule contains: Molnupiravir 200 mg

Excipients q.s.

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Hard Hypromellose Capsule

A size "0" white Opaque Cap and White Opaque Body, Hard Hypromellose Capsules filled with white to off-white powder, imprinted axially with "M200" on Cap and V on Body with black ink.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Molnupiravir Capsules 200 mg is indicated for treatment of adult patients with COVID-19, with SpO2>93% and who have high risk of progression of the disease including hospitalization or death. (see sections 4.2 and 5.1 for information on posology and limits of clinical trial population).

4.2 Posology and method of administration

Posology

Adults

The recommended dose of molnupiravir is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days.

The safety and efficacy of molnupiravir when administered for periods longer than 5 days have not been established (see section 5.1).

Molnupiravir should be administered as soon as possible after a diagnosis of COVID-19 has been made and within 5 days of symptom onset (see section 5.1).

Missed dose

If the patient misses a dose of molnupiravir within 10 hours of the time it is usually taken, the patient should take as soon as possible and resume the normal dosing schedule. If a patient misses a dose by more than 10 hours, the patient should not take the missed dose and instead take the next dose at the regularly scheduled time. The patient should not double the dose to make up for a missed dose.

Special populations

Elderly

No dose adjustment of molnupiravir is required based on age (see section 5.2).

Renal impairment

No dose adjustment is required for patients with renal impairment (see section 5.2).

Hepatic impairment

No dose adjustment is required for patients with hepatic impairment (see section 5.2).

Paediatric population

The safety and efficacy of molnupiravir in patients below 18 years of age have not been established. No data are available (see section 5.1).

Method of administration

For oral use.

Molnupiravir 200 mg capsules can be taken with or without food.

The capsules should be swallowed whole with a sufficient amount of fluid (e.g., a glass of water). The capsules should not be opened, crushed or chewed.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Sodium

This medicinal product contains 0.962 mg of sodium per capsule.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions have been identified based on the limited available data. No clinical interaction studies have been performed with molnupiravir. Molnupiravir is hydrolysed to n-hydroxycytidine (NHC) prior to reaching systemic circulation. Uptake of NHC and metabolism to NHC-TP are mediated by the same pathways involved in endogenous pyrimidine metabolism. NHC is not a substrate of major drug metabolising enzymes or transporters. Based on *in vitro* studies, neither molnupiravir nor NHC are inhibitors or inducers of major drug metabolising enzymes or inhibitors of major drug transporters. Therefore, the potential for molnupiravir or NHC to interact with concomitant medications is considered unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of molnupiravir in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

Molnupiravir is not recommended during pregnancy. Women of childbearing potential should use effective contraception for the duration of treatment and for 4 days after the last dose of Molnupiravir (molnupiravir).

Male of reproductive potential who are sexually active with female of child bearing potential should use reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.

Breast-feeding

It is unknown whether molnupiravir or any of the components of molnupiravir are present in human milk, affect human milk production, or have effect on the breastfed infant. Animal lactation studies with molnupiravir have not been conducted.

Based on the potential for adverse reactions on the infant from Molnupiravir, breast-feeding is not recommended during treatment and for 4 days after the last dose of Molnupiravir.

Fertility

There were no effects on female or male fertility in rats at NHC exposures approximately 2 and 6 times respectively, the exposure in humans at the recommended human dose (RHD) (see section 5.3).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Summary of safety profile

In an interim analysis of a Phase 3 trial of subjects with mild to moderate Covid-19 treated with molnupiravir (n=386), the most common adverse reactions (≥1% of subjects) reported during treatment and during 14 days after the last dose were diarrhoea (3%), nausea (2%), dizziness (1%) and headache (1%) all of which were Grade 1 (mild) or Grade 2 (moderate).

Tabulated list of adverse reactions

The adverse reactions are listed below by system organ class and frequency. Frequencies are defined as follows: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000).

Table 1: Tabulated list of adverse reactions

Frequency	Adverse Reaction
Nervous system disorders	
Common	dizziness, headache
Gastrointestinal disorders	
Common	diarrhoea, nausea
Uncommon	vomiting
Skin and subcutaneous tissue disorders	
Uncommon	rash, urticaria

Phase 3 Consortium study done in India

Safety profile in the interim analysis of the ongoing phase 3 clinical study titled 'A Prospective, Randomized, Multicenter, open label, Parallel Group, Phase III Trial to Evaluate Safety and Efficacy of Oral Molnupiravir as add on to Standard supportive Care for treatment of Mild Patients with COVID-19 Disease in a subset of 823 subjects was as follows:

- Molnupiravir 800 mg orally twice daily for 5 days was generally well tolerated
- Incidence of AE and drug related AE was comparable between Molnupiravir and Placebo arm
- Only one SAE (in the placebo arm) was considered drug-related by the investigator and most SAEs were COVID-19 related.

Table 2: Treatment Emergent Adverse Events

Parameter, n (%)	Molnupiravir + SOC (N = 363)	SOC (N = 367)
Abdominal pain	1 (0.3%)	0
Diarrhea	1 (0.3%)	0
Gastritis	3 (0.8%)	0
Nausea	4 (1.1%)	0
Chills	0	1 (0.3%)
Fatigue	1 (0.3%)	0
Malaise	2 (0.6%)	0
Pyrexia	3 (0.8%)	3 (0.8%)
COVID Pneumonia	0	1 (0.3%)
Sinusitis	1 (0.3%)	0
Muscle Spasm	0	2 (0.6%)
Myalgia	3 (0.8%)	0
Aguesia	1 (0.3%)	0
Headache	2 (0.6%)	1 (0.3%)
Sleep deficit	1 (0.3%)	0
Nephrolithiasis	0	1 (0.3%)
Cough	1 (0.3%)	0
Erythema	0	1 (0.3%)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system and write to ProductSafety@viatris.com.

4.9 Overdose

There is no human experience of overdosage with molnupiravir. Treatment of overdose with molnupiravir should consist of general supportive measures including the monitoring of the clinical status of the patient. Haemodialysis is not expected to result in effective elimination of NHC.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antivirals for systemic use, direct acting antivirals, ATC code: not yet assigned.

Mechanism of action

Molnupiravir is a prodrug that is metabolised to the ribonucleoside analogue N-hydroxycytidine (NHC) which distributes into cells where it is phosphorylated to form the pharmacologically active ribonucleoside triphosphate (NHC-TP). NHC-TP acts by a mechanism known as viral error catastrophe. NHC-TP incorporation into viral RNA by the viral RNA polymerase, results in an accumulation of errors in the viral genome leading to inhibition of replication.

Antiviral Activity

NHC was active in cell culture assays against SARS-CoV-2 with 50% effective concentrations (EC_{50}) ranging between 0.67 to 2.66 μM in A-549 cells and 0.32 to 2.03 μM *in Vero* E6 cells. NHC had similar activity against SARS-CoV-2 variants B.1.1.7 (Alpha), B.1351 (Beta), P.1 (Gamma), and B.1.617.2 (Delta) with EC_{50} values of 1.59, 1.77 and 1.32 and 1.68 μM, respectively. No impact was observed on the *in vitro* antiviral activity of NHC against SARS-CoV-2 when NHC was tested in combination with abacavir, emtricitabine, hydroxychloroquine, lamivudine, nelfinavir, remdesivir, ribavirin, sofosbuvir, or tenofovir.

Pharmacodynamic effects

The relationship between NHC and intracellular NHC-TP with antiviral efficacy has not been evaluated clinically.

Resistance

No amino acid substitutions in SARS-CoV-2 associated with resistance to NHC have been identified in Phase 2 clinical trials evaluating molnupiravir for the treatment of COVID-19. Studies to evaluate selection of resistance to NHC with SARS-CoV-2 in cell culture have not been completed.

Clinical efficacy and safety

Clinical data are based on an interim analysis of data from 775 randomised subjects in the Phase 3 MOVe-OUT trial. MOVe-OUT was a randomised, placebo-controlled, double-blind clinical trial studying molnupiravir for the treatment of non-hospitalised patients with mild to moderate COVID-19 who were at risk for progressing to severe COVID-19 and/or hospitalisation. **Eligible subjects were 18 years of age and older and had one or more pre-defined risk factors for disease progression: 60 years of age or older, diabetes, obesity (BMI >30), chronic kidney disease, serious heart conditions, chronic obstructive pulmonary disease, or active cancer. The study included symptomatic subjects not vaccinated against SARS-CoV-2 and who had laboratory confirmed SARS-CoV-2 infection and symptom onset within 5 days of enrolment.** Subjects were randomised 1:1 to receive 800 mg of molnupiravir or placebo orally twice daily for 5 days.

At baseline, in all randomised subjects, the median age was 44 years (range: 18 to 88 years); 14% of subjects were 60 years of age or older and 3% were over 75 years of age; 52% of subjects were male; 52% were White, 6% Black or African American, 2% Asian; 58% were Hispanic or Latino. Forty-nine percent of subjects received Molnupiravir or placebo within 3 days of COVID-19 symptom onset. The most common risk factors were obesity (77%), 60 years of age or older (14%), and diabetes (14%). Overall, baseline demographic and disease characteristics were well balanced between the treatment arms.

Table 3 provides the results of the primary endpoint (the percentage of subjects who were hospitalised or died through Day 29 due to any cause). Treatment with Molnupiravir resulted in a 6.8 percentage point reduction in the risk of hospitalisation or death (approximately 50% relative risk reduction). All 8 subjects who died through Day 29 were in the placebo group and were hospitalised prior to their death.

Table 3: Interim Efficacy Results in Non-Hospitalised Adults with COVID-19

	Molnupiravir (N=385) n (%)	**Placebo (N=377) n (%)**	***Risk difference* (95% CI)***	***p-value***
All-cause hospitalisation or death through Day 29†	28 (7.3%)	53 (14.1%)	-6.8 (-11.3, -2.4)	0.0012
Hospitalisation	28 (7.3%)	52 (13.8%)		
Death	0 (0%)	8 (2.1%)		
Unknown‡	0 (0%)	1 (0.3%)		

* Risk difference of molnupiravir-placebo based on Miettinen and Nurminen method stratified by time of COVID-19 symptom onset (≤3 days vs. >3 [4-5] days).

† Defined as ≥24 hours of acute care in a hospital or an acute care facility (e.g., emergency room).

‡ Subjects with unknown status at Day 29 are counted as having an outcome of all-cause hospitalisation or death in the efficacy analysis.

Note: All subjects who died through Day 29 were hospitalised prior to death.

Efficacy results were consistent across sub-groups including age (>60 years), at risk medical conditions (e.g., obesity, diabetes) and SARS-CoV-2 variants.

Phase 3 Consortium study done in India

A Prospective, Randomized, Multicenter, open label, Parallel Group, compared to standard of care Phase III Trial to Evaluate Safety and Efficacy of Oral Molnupiravir as add on to Standard supportive Care for treatment in Mild Patients with COVID-19 Disease. This study plans to enroll 1218 patients.

Interim analysis was conducted when 75% subjects (411 in test arm vs. 412 in SOC arm) were enrolled. Analysis of 800 subjects is presented- **Interim results of 800 (app 75%) subjects till day 14 indicate significantly faster clinical improvement:** Faster RT-PCR negativity, Better symptomatic reduction per WHO scale, higher reduction in viral load, and reduction in inflammatory marker (CRP) e and with faster as well as higher reductions in the SARS-Cov-2 viral load, which is expected to translate into better clinical outcomes in due course of follow-up.

Primary endpoint; only 1 patient hospitalized in SOC arm

Secondary endpoints: RT-PCR Negativity-No Significant Difference was observed in High Risk Population except for D5 where 83.5% vs 77.8% subjects showed improvement with Molnupiravir

Time to Clinical Improvement- Statistically significant difference at Day 5 and 10 was observed in both 1 point improvement and 2 point improvement on WHO cardinal scale in Molnupiravir arm.

Time to achieve at least one-point improvement in 11-Point ordinal scale by WHO			**Time to achieve at least two-point improvement in 11-Point ordinal scale by WHO**	
Parameter	**Molnupiravir 800 mg +SOC (N=406)**	**SOC (N=405)**	**Molnupiravir 800 mg +SOC (N=406)**	**SOC (N=405)**
N	401	398	383	383
N1	5	7	23	22
Median time [1]	5	5	6	9
95% CI for Median	(NE:NE)	(5:6)	(5:6)	(NE:NE)
Q1:Q3	5:9	5:10	5:10	5:13
p-value [2]	<.0001		<.0001	

- Molnupiravir addition to SOC significantly reduces the viral load at D5 and D10 in overall population. In high risk group it shows numerical improvement
- Relief of Specific Symptoms(fever, cough, loss of smell and loss of taste-Overall)- India study shows improvements in line with Merck Study
- Molnupiravir Leads to Greater Reduction in the CRP values in Patients with High Baseline CRP

Pediatric population

This medicine is not recommended for children and adolescents under 18 years due to the lack of data in these patients.

5.2 Pharmacokinetic properties

Molnupiravir is a 5´-isobutyrate prodrug that is hydrolysed to NHC prior to reaching systemic circulation. The pharmacokinetics of NHC are similar in healthy subjects and patients with COVID-19.

The pharmacokinetics of NHC at steady-state following administration of 800 mg molnupiravir every 12 hours are provided below in Table 4.

Table 4: Pharmacokinetics of NHC after administration of 800mg Molnupiravir every 12 hours

NHC Geometric Mean (%CV)		
$AUC_{0\text{-}12hr}$ (ng×hr/mL)*	C_{max} (ng/mL) †	C_{12hr} (ng/mL)*
8260 (41.0)	2970 (16.8)	31.1 (124)
%CV: Geometric coefficient of variation. * Values were obtained from population PK analysis. †Values were obtained from a Phase 1 study of healthy subjects.		

Absorption

Following twice daily oral administration of 800 mg molnupiravir, the median time to peak plasma NHC concentrations (T_{max}) was 1.5 hours.

Effect of Food on Oral Absorption

In healthy subjects, the administration of a single 200 mg dose of molnupiravir with a high-fat meal resulted in a 35% reduction in NHC peak concentrations (C_{max}), AUC was not significantly affected.

Distribution

NHC does not bind to plasma proteins.

Elimination

The effective half-life of NHC is approximately 3.3 hours. The fraction of dose excreted as NHC in the urine was ≤3% in healthy participants.

Other special populations

Gender, Race, Age

Population pharmacokinetic analysis showed that age, gender, race and ethnicity do not meaningfully influence the pharmacokinetics of NHC.

Paediatric Patients

Molnupiravir has not been studied in paediatric patients.

Renal Impairment

Renal clearance is not a meaningful route of elimination for NHC. No dose adjustment in patients with any degree of renal impairment is needed. In a population PK analysis, mild or moderate renal impairment did not have a meaningful impact on the pharmacokinetics of NHC. The pharmacokinetics of molnupiravir and NHC has not been evaluated in patients with eGFR less than 30 mL/min or on dialysis (see section 4.2).

Hepatic Impairment

The pharmacokinetics of molnupiravir and NHC has not been evaluated in patients with hepatic impairment. Preclinical data indicate that hepatic elimination is not expected to be a major route of NHC elimination therefore hepatic impairment is unlikely to affect NHC exposure. No dose adjustment in patients with hepatic impairment is needed (see section 4.2).

5.3 Preclinical safety data

General Toxicity

Reversible, dose-related bone marrow toxicity affecting all haematopoietic cell lines was observed in dogs at ≥17 mg/kg/day (0.4 times the human NHC exposure at the recommended human dose (RHD)). Mild decreases in peripheral blood cell and platelet counts were seen after 7 days of molnupiravir treatment progressing to more severe haematological changes after 14 days of treatment. Neither bone marrow nor haematological toxicity was observed in a 1-month toxicity study in mice up to 2,000 mg/kg/day (19 times the human NHC exposure at the RHD) and a 3-month toxicity study in rats up to 1,000 mg/kg/day (9.3 and 15 times the human NHC exposure at the RHD in females and males, respectively).

Bone and cartilage toxicity, consisting of an increase in the thickness of physeal and epiphyseal growth cartilage with decreases in trabecular bone was observed in the femur and tibia of rapidly growing rats in a 3-month toxicity study at ≥ 500 mg/kg/day (5.4 times the human NHC exposure at the RHD). There was no bone or cartilage toxicity in a 1-month toxicity study in rapidly growing rats up to 500 mg/kg/day (4.2 and 7.8 times the human NHC exposure at the RHD in females and males, respectively), in dogs dosed for 14 days up to 50 mg/kg/day (1.6 times the human NHC exposure at the RHD), or in a 1-month toxicity study in mice up to 2,000 mg/kg/day (19 times the human NHC exposure at the RHD). Growth cartilage is not present in mature skeletons; therefore the bone and cartilage findings are not relevant for adult humans. The clinical significance of these findings for paediatric patients is unknown.

Carcinogenesis

Carcinogenicity studies with molnupiravir have not been conducted.

Mutagenesis

Molnupiravir and NHC were positive in the *in vitro* bacterial reverse mutation assay (Ames assay) with and without metabolic activation. In 2 distinct *in vivo* rodent mutagenicity models (Pig-a mutagenicity assay and Big Blue® (cII Locus) transgenic rodent assay) molnupiravir did not induce increased mutation rates relative to untreated historical control animals, and therefore is not mutagenic *in vivo*. Molnupiravir was negative for induction of chromosomal damage in *in vitro* micronucleus (with and without metabolic activation) and *in vivo* rat micronucleus assays. Based on the totality of the genotoxicity data, molnupiravir is of low risk for genotoxicity or mutagenicity in clinical use.

Impairment of Fertility

There were no effects on fertility, mating performance or early embryonic development when molnupiravir was administered to female or male rats at NHC exposures approximately 2 and 6 times, respectively, the human NHC exposure at the recommended human dose (RHD).

Development

In an embryofoetal development (EFD) study in rats, molnupiravir was administered orally to pregnant rats at 0, 100, 250, or 500 mg/kg/day from gestation days (GDs) 6 to 17. Molnupiravir was also administered orally to pregnant rats at up to 1,000 mg/kg/day from GDs 6 to 17 in a preliminary EFD study. Developmental toxicities included post-implantation losses, malformations of the eye, kidney, and axial skeleton, and rib variations at 1,000 mg/kg/day (8 times the human NHC exposure at the RHD) and decreased foetal body weights and delayed ossification at ≥500 mg/kg/day (2.9 times the human NHC exposure at the RHD). There were no developmental toxicities at ≤250 mg/kg/day (0.8 times the human NHC exposure at the RHD). Maternal toxicities included decreased food consumption and body weight losses, resulting in the early sacrifice of individual animals at 1,000 mg/kg/day, and decreased body weight gain at 500 mg/kg/day.

In an EFD study in rabbits, molnupiravir was administered orally to pregnant rabbits at 0, 125, 400, or 750 mg/kg/day from GDs 7 to 19. Developmental toxicity was limited to reduced foetal body weights at 750 mg/kg/day (18 times the human NHC exposures at the RHD). There was no developmental toxicity at ≤400 mg/kg/day (7 times the human NHC exposures at the RHD). Maternal toxicities included reduced food consumption and body weight gains, and abnormal faecal output at 750 mg/kg/day.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropyl cellulose, Microcrystalline Cellulose, croscarmellose Sodium, Magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Refer to Carton

6.4 Special precautions for storage

Do not store above 30°C. Store in the original container.

6.5 Nature and contents of Blister pack

40's Bottle pack (without desiccant)*

40's Bottle pack (with desiccant)*

10's Cold form blister (Box of 4 blisters × 10's Capsules)*

* Not all pack sizes may be marketed

6.6 Instructions for use and handling and disposal

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

7. Manufacturer

Manufactured By:

Mylan Laboratories Limited

F-4 & F-12, MIDC, Malegaon, Sinnar,

Nashik - 422 113, Maharashtra, INDIA

Marketed in India By:

Mylan Pharmaceuticals Pvt. Ltd.

Room No. 2, Minus 3rd Floor, Plot No. 564/A/22, Road No. 92,

Jubilee Hills, Ameerpet, Hyderabad, Telangana – 500 096, INDIA

Reference

Summary of Product Characteristics of Lagevrio 200 mg hard capsules, Updated 05-Nov-2021 | Merck Sharp & Dohme (UK) Limited, available at https://www.medicines.org.uk/emc/product/13044/smpc as accessed on November 8, 2021.

MOLNATRIS is manufactured under a license from MERCK SHARP & DOHME SINGAPORE TRADING PTE. LTD

To be distributed and used in licensed countries only.

For reporting of adverse events and PV related queries please write on Email: ProductSafety@viatris.com

---

Package leaflet: Information for the patient

℞ Molnupiravir Capsules 200 mg

MOLNATRIS™

Important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Molnupiravir is and what it is used for

Molnupiravir Capsules 200 mg contains the active substance molnupiravir. Molnupiravir is an antiviral medicine used to treat adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death. Molnupiravir may help people with COVID-19 stay out of the hospital and feel better.

2. What you need to know before you take Molnupiravir

Do not take Molnupiravir

- if you are allergic to molnupiravir or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking molnupiravir.

Children and adolescents

Do not give this medicine to children and adolescents aged less than 18 years. The use of Molnupiravir in persons aged less than 18 years has not yet been studied.

Other medicines and Molnupiravir

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Animal studies with molnupiravir have shown harmful effects to the unborn animal. **Molnupiravir is not recommended in pregnancy.** Molnupiravir has not been studied in pregnancy and it is not known if Molnupiravir will harm your baby while you are pregnant.

- **If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice. If you can become pregnant, you should use effective birth control while you are taking Molnupiravir and for 4 days after the last dose of Molnupiravir.**
- If you are breast-feeding or are planning to breastfeed, tell your doctor before taking this medicine. **Breast-feeding is not recommended during treatment and for 4 days after the last dose of Molnupiravir.** This is because it is not known if Molnupiravir gets into breast milk and will be passed to the baby. Male of reproductive potential who are sexually active with female of child bearing potential should use reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Molnupiravir contains sodium

This medicinal product contains 0.962 mg of sodium per capsule.

3. How to take Molnupiravir

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should start Molnupiravir within 5 days of the onset of COVID-19 symptoms.

How much to take

The recommended dose of Molnupiravir is four 200 mg capsules, every 12 hours for 5 days.

How to take

- Swallow the capsule whole with plenty of fluid (for instance a glass of water)
- Do not open, break, or crush the capsules.
- This medicine can be taken with or without food.

If you take more Molnupiravir than you should

If you take more Molnupiravir than you should, contact your doctor straight away.

If you forget to take Molnupiravir

- It is important that you do not miss or skip doses of this medicine.
- If you forget to take a dose within 10 hours of the time it is usually taken, you should take it as soon as possible and take the next one at the usual time.
- If you forget to take a dose by more than 10 hours, you should not take the missed dose and instead take the next one at the usual time.
- Do not take a double dose to make up for a missed dose.
- If you are not sure what to do, call your doctor or pharmacist.

Do not stop taking Molnupiravir

Do not stop taking Molnupiravir without talking to your doctor first. This will give the medicine the best chance to keep you from becoming severely ill from COVID-19.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

- diarrhoea
- nausea
- feeling dizzy
- headache

Uncommon: may affect up to 1 in 100 people

- vomiting
- rash
- hives

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can write to ProductSafety@viatris.com. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Molnupiravir

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP.

The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Molnupiravir contains

The active substance is molnupiravir. Each hard capsule contains 200 mg of molnupiravir.

The other ingredients are:

Hydroxypropyl cellulose, Microcrystalline Cellulose, croscarmellose Sodium, Magnesium stearate.

What Molnupiravir looks like and contents of the pack

Hard Hypromellose Capsule

A size "0" white Opaque Cap and White Opaque Body, Hard Hypromellose Capsules filled with white to off-white powder, imprinted axially with "M200" on Cap and V on Body with black ink.

40's Bottle pack (without desiccant)*

40's Bottle pack (with desiccant)*

10's Cold form blister (Box of 4 blisters × 10's Capsules)*

* Not all pack sizes may be marketed

7. Manufacturer

Manufactured By:

Mylan Laboratories Limited

F-4 & F-12, MIDC, Malegaon, Sinnar,

Nashik - 422 113, Maharashtra, INDIA

Marketed in India By:

Mylan Pharmaceuticals Pvt. Ltd.

Room No. 2, Minus 3rd Floor, Plot No. 564/A/22, Road No. 92,

Jubilee Hills, Ameerpet, Hyderabad, Telangana – 500 096, INDIA

This leaflet was last approved in December 2021

MOLNATRIS is manufactured under a license from MERCK SHARP & DOHME SINGAPORE TRADING PTE. LTD

To be distributed and used in licensed countries only.

Mfg. Lic. No.: NKD/89

Visit us at: **www.mylan.in**

™ Trademark under Registration

Mylan