Molnupiravir (Lexi-Drugs)

Pronunciation
(MOL nue PIR a vir)

Brand Names: US
Lagevrio

Pharmacologic Category
Antiviral Agent

Dosing: Adult
COVID-19, mild to moderate; treatment

COVID-19, mild to moderate; treatment (alternative agent):

Note: For patients at high risk of progression to severe COVID-19, including hospitalization or death (Ref).

Oral: 800 mg every 12 hours for 5 days; initiate as soon as possible after COVID-19 diagnosis, and within 5 days of symptom onset. After initiating treatment with molnupiravir, if hospitalization is required, completion of 5-day course is at the health care provider's discretion (Ref).

Missed dose: If a dose is missed within 10 hours of usual administration time, administer the missed dose as soon as possible, and resume normal dosing schedule. If a dose is missed by more than 10 hours, do not administer the missed dose, and resume dosing at the next scheduled administration time. Do not double the dose to make up for a missed dose (Ref).

* See Dosage and Administration in AHFS Essentials for additional information.

Dosing: Older Adult

Refer to adult dosing.

Dosing: Altered Kidney Function: Adult

No dosage adjustment necessary (Ref).

Dosing: Hepatic Impairment: Adult

No dosage adjustment necessary (Ref).

Dosing: Pediatric

Note: Do not use in patients <18 years of age due to the potential for bone and cartilage toxicity (Ref).

COVID-19, mild to moderate; treatment
COVID-19, mild to moderate; treatment (outpatients with high risk of progression to severe illness) (alternative agent):

Adolescents ≥18 years: Oral: 800 mg every 12 hours for 5 days; initiate as soon as possible after COVID-19 diagnosis, and within 5 days of symptom onset. After initiating treatment with molnupiravir, if hospitalization is required, completion of 5-day course is at the health care provider's discretion (Ref).

Dosing: Altered Kidney Function: Pediatric
Adolescents ≥18 years: No dosage adjustment necessary (Ref).

Dosing: Hepatic Impairment: Pediatric
Adolescents ≥18 years: No dosage adjustment necessary (Ref).

Use: Labeled Indications
See "Use: Off Label."

* See Uses in AHFS Essentials for additional information.

Use: Off-Label: Adult
COVID-19, treatment, mild to moderate (alternative agent)Level of Evidence [C, G]

Data from a phase 3 randomized, double-blind, placebo-controlled trial in unvaccinated, nonhospitalized, adults with mild to moderate laboratory-confirmed SARS-CoV-2 infection suggest that molnupiravir may be beneficial in preventing the progression to hospitalization and/or death (Ref). In an open-label, randomized trial in vaccinated, nonhospitalized adults with increased risk for adverse outcomes, molnupiravir did not reduce progression to hospitalization or death; however, time to improvement of symptoms was reduced (Ref). Under the emergency use authorization and based on the National Institutes of Health COVID-19 guidelines, use should be limited to treatment of mild to moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate (Ref).

Limitations of use: Not authorized for patients <18 years of age, initiation of treatment in patients hospitalized due to COVID-19, for pre-exposure or postexposure prophylaxis for prevention of COVID-19; or for use longer than 5 consecutive days (Ref).

Note: Medical conditions and factors associated with increased risk for progression to severe COVID-19 have been identified by the Centers for Disease Control and Prevention and can be found at https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html. This list is not exhaustive and is updated as the science evolves. Consider the benefit:risk for an individual patient (Ref).

Level of Evidence Definitions

Level of Evidence Scale
A - Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support the off-label use. Further research is unlikely to change confidence in the estimate of benefit.

B - Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.

C - Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care), unsystematic clinical experience, or from potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.

G - Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

Clinical Practice Guidelines

IDSA, "Guidelines on the Treatment and Management of Patients With COVID-19"

NIH, "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines"

Administration: Oral

Administer with or without food. Swallow capsules whole; do not open, break, or crush (Ref).

Administration: Other

Nasogastric or orogastric feeding tube (NG or OG tube): Open capsules and transfer contents to a container with a lid; add 40 mL of water to the container and shake thoroughly (3 minutes). Flush NG/OG tube with 5 mL of water prior to administration; draw up entire contents in container using a catheter-tip syringe and administer immediately through the NG/OG tube (≥12F). If contents remain in container, add 10 mL of water to the container, mix, and draw up into the same syringe administering via the NG/OG tube; repeat as needed until container and syringe are empty. Flush NG/OG tube twice with 5 mL of water (10 mL total) after administering the mixture. Note: Capsule contents may not dissolve completely and visible undissolved particulates are acceptable; do not store mixture for future use (Ref).

Administration: Pediatric

Oral: Administer with or without food. Swallow capsules whole; do not open, break, or crush (Ref).

Nasogastric (NG) or orogastric (OG) tube (12 French or larger): Empty 4 capsules (800 mg) into a clean container with a lid. Add 40 mL water, close the lid, and shake for 3 minutes; capsule contents may not completely dissolve; undissolved particles are acceptable to administer. Flush NG or OG tube with 5 mL water, then administer prepared mixture immediately using a catheter tip syringe. If any capsule contents remain in container, add 10 mL of water, mix, and administer through the NG or OG tube with the same syringe; repeat as needed until no capsule contents remain in syringe or container. After administering the full dose, flush the NG or OG tube with 5 mL of water twice (10 mL total).
**Missed dose:** If a dose is missed within 10 hours of usual administration time, administer the missed dose as soon as possible, and resume normal dosing schedule. If a dose is missed by >10 hours, do not administer the missed dose, and resume dosing at the next scheduled administration time. Do not double the dose to make up for a missed dose (Ref).

**Storage/Stability**

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) (FDA 2023).

**Patient Counseling Points**

**What is this drug used for?**

• It is used in certain people to treat COVID-19.

**All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:**

• Diarrhea
• Upset stomach
• Dizziness

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• A fast heartbeat
• Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

Molnupiravir FDA fact sheets – [Health care provider; Patient](https://www.fda.gov/Drugs/Drugs-by-Class/Medicines-to-Treat-COVID-19/Molnupiravir)

**Note:** This is not a comprehensive list of all side effects. Talk to your doctor if you have questions.

**Consumer Information Use and Disclaimer:** This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a limited summary of general information about the medicine's uses from the patient education leaflet and is not intended to be comprehensive. This limited summary does NOT include all information available about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not intended to provide medical advice, diagnosis or treatment and does not replace information you receive from the healthcare provider. For a more detailed summary of information about the risks and benefits of using this medicine, please speak with your healthcare provider and review the entire patient education leaflet.
Prescribing and Access Restrictions

Molnupiravir is not commercially available; it is available as part of ongoing clinical trials and under an emergency use authorization (EUA) from the FDA. Molnupiravir is available from the distributor, AmerisourceBergen.

As part of the EUA, information consistent with fact sheets pertaining to emergency use of molnupiravir are required to be available for health care providers and patients/caregivers, and certain mandatory requirements for molnupiravir administration under the EUA must be met as outlined in the FDA EUA letter; the fact sheets may be accessed at https://www.molnupiravir.com. Additionally, health care providers must track and report all medication errors and serious adverse events potentially associated with molnupiravir use by either submitting a MedWatch form (https://www.fda.gov/medwatch/report.htm), FDA Form 3500 (health professional; available at: https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500) by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or fax (1-800-FDA-0178), or by calling 1-800-FDA-1088 to request a reporting form; a copy of all MedWatch forms should also be provided to Merck & Co., Inc. (phone: 1-800-672-6372; fax: 1-215-616-5677; e-mail: dpoc.usa@msd.com).

Contraindications

There are no contraindications listed in the FDA emergency use authorization (EUA) fact sheet for health care providers.

Warnings/Precautions

Concerns related to adverse effects:

• Bone and cartilage effects: Bone and cartilage toxicity was observed in animals after repeat dosing; molnupiravir is not authorized for use in patients <18 years of age because it may affect bone and cartilage growth (FDA 2023).

• Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, have been reported. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care (FDA 2023).

* See Cautions in AHFS Essentials for additional information.

Older Adult Considerations

In the MOVE-OUT trial, 11% of patients were ≥65 years of age. No differences in safety, efficacy, or pharmacokinetics between older and younger adults.

Reproductive Considerations

Evaluate and verify pregnancy status prior to use in patients who may become pregnant.

Pregnancy testing is recommended for patients who do not have regular menstrual cycles, who are unsure of the first day of their last cycle, or who do not use contraception correctly and consistently. Pregnancy status does not need confirmed in patients using an intrauterine system or contraceptive
implant, patients who have undergone permanent sterilization, or when pregnancy is otherwise not possible.

Patients who may become pregnant should use reliable contraception correctly and consistently during therapy and for 4 days after the last dose of molnupiravir. Sexually active males with partners who may become pregnant should also use effective contraception during therapy and for at least 3 months after the last molnupiravir dose.

**Pregnancy Considerations**

Based on data from animal reproduction studies, in utero exposure to molnupiravir may cause fetal harm. Molnupiravir is currently available under FDA emergency use authorization (EUA) for the treatment of COVID-19; pregnant patients were not eligible for inclusion in a phase 3 study (Jayk Bernal 2021).

The risk of severe illness from COVID-19 infection is increased in symptomatic pregnant patients compared to nonpregnant patients. Pregnant and recently pregnant patients with moderate or severe infection are at increased risk of complications such as hypertensive disorders of pregnancy, postpartum hemorrhage, or other infections compared to pregnant patients without COVID-19. Symptomatic pregnant patients may require ICU admission, mechanical ventilation, or ventilatory support (ECMO) compared to symptomatic nonpregnant patients. Other adverse pregnancy outcomes include preterm birth and stillbirth. The risk of coagulopathy, cesarean delivery, and maternal death may be increased; neonates have an increased risk for NICU admission. Maternal age and comorbidities such as diabetes, hypertension, lung disease, and obesity may also increase the risk of severe illness in pregnant and recently pregnant patients (ACOG 2022; NIH 2022).

In general, the treatment of COVID-19 infection during pregnancy is the same as in nonpregnant patients. However, because data for most therapeutic agents in pregnant patients are limited, treatment options should be evaluated as part of a shared decision-making process (NIH 2022). Use of molnupiravir in pregnancy is not recommended unless no other options are available, and therapy is clearly indicated. In pregnant patients at high risk of progressing to severe disease, use may be considered after the period of embryogenesis (eg, >10 weeks' gestation) when preferred treatments are not available (NIH 2022). If the decision is made to use molnupiravir in a pregnant patient, the prescriber must document that the known and potential risks, as outlined in the Fact Sheet for Patients and Caregivers, have been communicated to the patient. Information related to the treatment of COVID-19 during pregnancy continues to emerge; refer to current guidelines for the treatment of pregnant patients.

Data collection to monitor pregnancy and infant outcomes following exposure to molnupiravir is ongoing. Health care providers must document that the pregnant patient was made aware of the molnupiravir pregnancy surveillance program. Health care providers must enroll patients who agree to participate ([https://covid-pr.pregistry.com](https://covid-pr.pregistry.com) or 1-800-616-3791, or by contacting the manufacturer at 1-877-888-4231). Patients may also enroll themselves.

**Breastfeeding Considerations**

It is not known if molnupiravir is present in breast milk.
Due to the potential for serious adverse reactions in the breastfed infant, breastfeeding is not recommended by the manufacturer during therapy and for 4 days after the last molnupiravir dose; patients may express and discard breast milk during this time.


**Adverse Reactions**

Adverse reactions and incidences are derived from the FDA-issued emergency use authorization (EUA). Adverse reactions reported in adults. Refer to EUA for information regarding reporting adverse reactions (FDA 2021).

**Postmarketing:**

Dermatologic: Erythema of skin, skin rash, urticaria

Hypersensitivity: Anaphylaxis, angioedema, hypersensitivity reaction

* See [Cautions in AHFS Essentials](#) for additional information.

**Metabolism/Transport Effects**

None known.

**Drug Interactions Open Interactions**

*Note:* Interacting drugs may not be individually listed below if they are part of a group interaction (eg, individual drugs within "CYP3A4 Inducers [Strong]" are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the Lexicomp drug interactions program by clicking on the "Open Interactions" button above.

Cladribine: Agents that Undergo Intracellular Phosphorylation may diminish the therapeutic effect of Cladribine. *Risk X: Avoid combination*

**Monitoring Parameters**

Pregnancy test prior to initiation, as clinically indicated (FDA 2023).

**Nursing Physical Assessment/Monitoring**

Monitor for signs and symptoms of hypersensitivity. Educate patient on when to seek immediate medical assistance.

**Product Availability**

Molnupiravir approved for emergency use authorization by the FDA December 2021.

**Dosage Forms: US**
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Capsule, Oral:

Lagevrio: 200 mg

**Generic Available (US)**

No

**Pricing: US**

Capsules (Lagevrio Oral)

200 mg (per each): $0.00

**Disclaimer:** A representative AWP (Average Wholesale Price) price or price range is provided as reference price only. A range is provided when more than one manufacturer’s AWP price is available and uses the low and high price reported by the manufacturers to determine the range. The pricing data should be used for benchmarking purposes only, and as such should not be used alone to set or adjudicate any prices for reimbursement or purchasing functions or considered to be an exact price for a single product and/or manufacturer. Medi-Span expressly disclaims all warranties of any kind or nature, whether express or implied, and assumes no liability with respect to accuracy of price or price range data published in its solutions. In no event shall Medi-Span be liable for special, indirect, incidental, or consequential damages arising from use of price or price range data. Pricing data is updated monthly.

**Mechanism of Action**

Molnupiravir is metabolized to the cytidine nucleoside analog, NHC, which is further phosphorylated to the active ribonucleoside triphosphate (NHC-TP). NHC-TP is incorporated into SARS-CoV-2 RNA by viral RNA polymerase, resulting in errors in viral genome and subsequently inhibition of replication (FDA 2023).

**Pharmacokinetics (Adult Data Unless Noted)**


Protein binding: NHC: Does not appear to be protein bound (FDA 2023).

Metabolism: Molnupiravir is metabolized to NHC; NHC undergoes phosphorylation to pharmacologically active ribonucleoside triphosphate.

Half-life elimination: NHC: 3.3 hours (FDA 2023).

Time to peak: NHC: 1.5 hours (FDA 2023).

Excretion: NHC: Urine (3%) (FDA 2023).

**Index Terms**

Coronavirus; COVID-19; EIDD-2801; MK-4482
FDA Approval Date
December 23, 2021

Brand Names: International

Find brand name(s) by country

References


Lagevrio (molnupiravir) [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; June 2022.


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