



Molnupiravir

- Mechanism: The oral prodrug of a ribonucleoside with activity against RNA viruses.
- Regimen: 800 mg PO twice daily for five days. Initiate within five days of symptom onset.
- Main concerns: Risk of fetal toxicity.

If considering administration in a village, a pharmacist MUST be consulted.

- Weekdays: Send message via Tiger Connect to "Village Ops Pharmacist."
- Weekends: Send message via Tiger Connect to "Inpatient Pharmacy."

Criteria:

- Age ≥18 years.
- Lab-confirmed COVID-19
- Mild to moderate disease in the outpatient setting
- High risk of progressing to severe illness.
- Alternative antiviral therapies not accessible or clinically appropriate.

No contraindications, warnings, or precautions.
(See box.)

Counsel patient and document per requirements in box.

- Prescribe molnupiravir as soon as possible after positive COVID test and within five days of symptom onset.
- Patient should take molnupiravir 800 mg (four 200 mg capsules) PO twice daily for five days.

Adverse Reactions

In the clinical studies quoted in the EUA, the following adverse events were reported: diarrhea, nausea, and dizziness.

Contraindications, Warnings, and Precautions

- Molnupiravir is NOT authorized for use in patients who are hospitalized, requiring supplemental oxygen, or requiring more than their baseline supplemental oxygen flow rates due to COVID.
- Pregnancy: Due to risk of fetal toxicity, molnupiravir is NOT recommended for use during pregnancy.
- Breastfeeding: Not recommended to breastfeed during treatment period and for four days after the last dose. Instruct patients to pump and discard milk.
- Patients with childbearing potential:
 - Females: Instruct patients to use effective contraception during the treatment period and for four days after the last dose.
 - Males: Instruct patients with partners of childbearing potential to use effective contraception during the treatment period and for three months after the last dose.
- <18 years: Due to risk of bone and cartilage growth disruption, molnupiravir is NOT recommended for patients younger than 18 years old.

Documentation Requirements for Molnupiravir

Communicate and document the following in the medical record:

- [Fact Sheet for Patients and Parents/Caregivers](#) given to patient/caregiver.
- Inform patient/caregiver of alternatives to receiving molnupiravir. See clinicaltrials.gov for emerging data.
- Inform patient/caregiver that molnupiravir is an unapproved drug that is authorized for use under Emergency Use Authorization.

Reporting of Adverse Events

The prescribing health care provider is responsible for mandatory reporting of all medication errors and adverse events potentially related to molnupiravir. Reports must be made within seven days of the event.

Serious adverse events include: death; life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant incapacity or substantial disruption of the ability to conduct normal life function; congenital anomaly/birth defect; or medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

Submit report to FDA MedWatch by completing the online form [here](#). The report should include "use of molnupiravir under Emergency Use Authorization (EUA)" in the "Describe Event" section.

See the [FDA MedWatch program](#) for more information.

Resource: Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Molnupiravir. Updated March 2022. Click [here](#) for source.

This guideline is designed for the general use of most patients but may need to be adapted to meet the special needs of a specific patient as determined by the medical practitioner.
Approved 6/6/22.

If comments about this guideline, please contact Leslie_Herrmann@ykhc.org.