COVID-19 THERAPEUTIC FACTSHEET: NIRMATRELVIR-RITONAVIR (Paxlovid)

Use: FDA Emergency Use Authorization (EUA) for the treatment of mild to moderate COVID-19 in **adults and pediatric patients (12 years and older and weight at least 40 kg)** at high risk for progression to severe COVID-19, including hospitalization or death.

Paxlovid Facts for Healthcare Providers - Summary	
Mechanism of Action	Viral protease inhibitor that inhibits SARS-CoV-2 replication plus a pharmacological booster (ritonavir)
Dosage/Administration	Nirmatrelvir 300mg (2 x 150mg tablets) plus Ritonavir 100mg (1 x 100mg tablet) PO Q12h x 5 days with/without food
Dose Adjustments	• In moderate renal impairment (eGFR ≥30 to <60 mL/min), reduce the dose to 150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days • Not recommended in those with estimated GFR <30 mL/min. • Not recommended in those with severe hepatic impairment.
EUA Inclusion Criteria	• Positive for SARS CoV-2 • High risk for progression to severe COVID 19, including hospitalization and death • 12 years of age and older • Weight 40 kg or more • Outpatient status or not hospitalized due to COVID-19 • Symptom onset </= 5 days
Contraindications	Contraindicated concomitant medication that risks significant drug-drug interactions (find details here)
Adverse Effects (<1%)	• Diarrhea • Altered taste • Hypertension • Myalgias
Drug Interactions	Many (find details here)

All patients should be provided with access to the **FDA Factsheet for Patients and Caregivers** and asked to review the information prior to starting treatment.

Renal Insufficiency

Laboratory testing prior to administration can lead to clinically significant delays in initiation of treatment, therefore, history should be obtained from the patient and available medical records reviewed for renal insufficiency including need for dialysis. Paxlovid is adjusted for renal function when eGFR <60 mL/min (see above).

Hepatic Impairment

Laboratory testing prior to administration can lead to clinically significant delays in initiation of treatment, therefore, history should be obtained from the patient and available medical records reviewed for severe hepatic impairment including cirrhosis.

Considerations for People Who Can Become Pregnant

Use of ritonavir may reduce the efficacy of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an effective alternative contraceptive method or an additional barrier method of contraception for 5-7 days after the start of therapy.

Considerations for People Who Are Pregnant

Paxlovid can be used in pregnant individuals. There are no available human data on the use of nirmatrelvir during pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Published observational studies on ritonavir use in pregnant women have not identified an increase in the risk of major birth defects. Published studies with ritonavir are insufficient to identify a drug-associated risk of miscarriage

Considerations During Lactation

There are no available data on the presence of nirmatrelvir in human or animal milk, the effects on the breastfed infant, or the effects on milk production. There is no information describing the effects of ritonavir on the breastfed infant or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for treatment and any potential adverse effects on the breastfed infant from Paxlovid or from the underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Considerations for Those Younger than 18 Years of Age

Paxlovid is not authorized for use in patients younger than 12 years of age or weighing less than 40 kg. Please consult Pediatric Infectious Diseases for therapeutic options.
The authorized adult dosing regimen is expected to result in comparable serum exposures of nirmatrelvir and ritonavir in patients 12 years of age and older and weighing at least 40 kg as observed in adults.

Handling Missed Doses

- If the patient misses a dose of Paxlovid within 8 hours of the time it is usually taken, the patient should take it as soon as possible and resume the normal dosing schedule.
- If the patient misses a dose by more than 8 hours, the patient should not take the missed dose and instead take the next dose at the regularly scheduled time.