
For people ages 12 and older

# XOCOVA is the first and only oral antiviral to help prevent COVID-19 after exposure[1,2]

- Proactive therapy against COVID-19 after exposure[1]
- Helps block viral replication before COVID-19 symptoms develop[1]
- Once-daily dosing: 7 tablets over a 5-day course of therapy[1]

Eligible commercially insured patients may pay **$0*** for XOCOVA

*Terms and conditions apply. Visit XocovaHCP.com for full terms and conditions and eligibility requirements

## INDICATION

XOCOVA (ensitrelvir) is indicated for post-exposure prophylaxis (PEP) of coronavirus disease 2019 (COVID-19) in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19.

## IMPORTANT SAFETY INFORMATION

**Contraindications**

XOCOVA is contraindicated in patients with a history of clinically significant hypersensitivity reactions to XOCOVA or any of its components. XOCOVA is also contraindicated when administered with drugs primarily metabolized by CYP3A for which elevated concentrations may be associated with serious and/or life-threatening reactions or when administered with strong CYP3A inducers because they may significantly reduce XOCOVA plasma concentrations leading to potential loss of virologic response.

**Please see additional Important Safety Information throughout and full Prescribing Information.**

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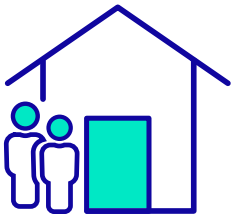
# Why is post-exposure prophylaxis (PEP) important?

## COVID-19 remains highly transmissible and continues to put patients and loved ones at risk[3-5]



### Household infections are fueling viral transmission in the wider community

- **43%–47% of household contacts** experienced a SARS-CoV-2 infection during the Omicron wave[3,4]
- COVID-19 is up to **3x more likely to spread in close-contact settings, such as households and long-term care facilities**[5]

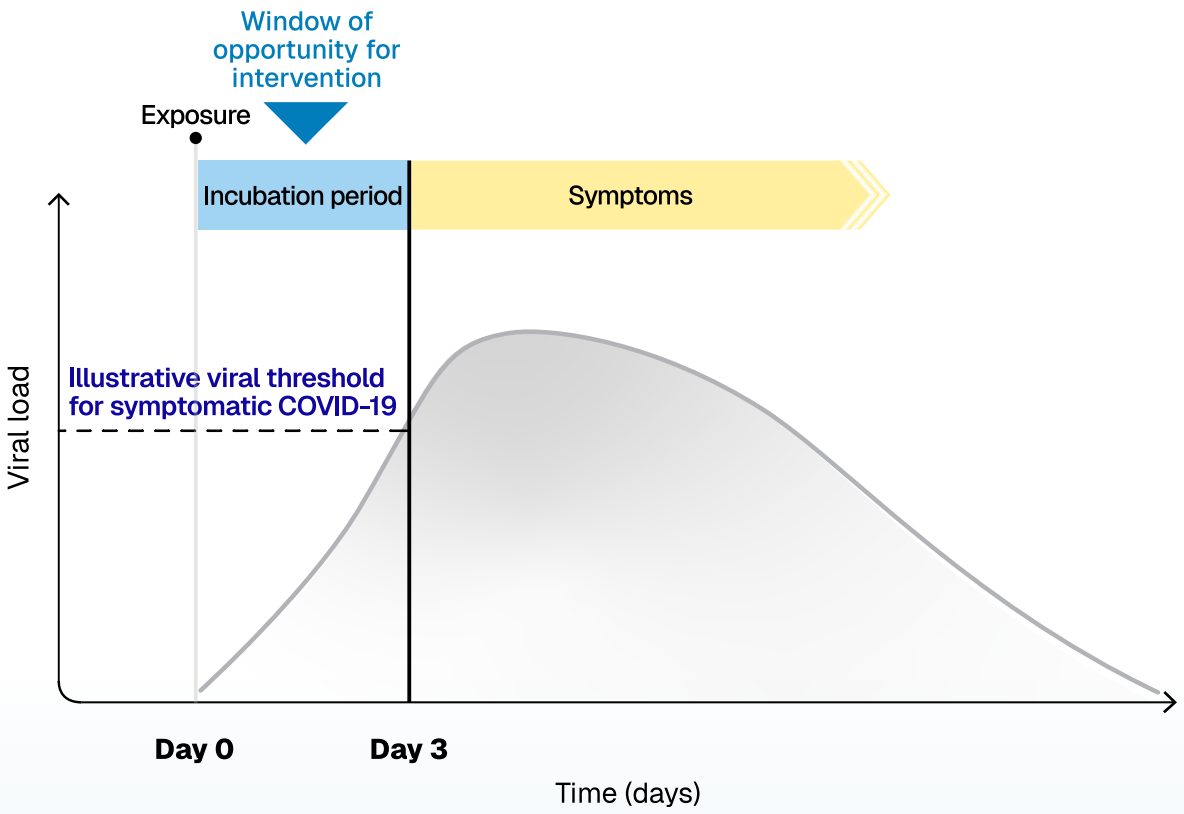
Low vaccination rates and vaccine efficacy limitations in certain patients may contribute to continued COVID-19 spread.[6,7]

### Most adults, due to factors such as age or comorbidities like obesity and diabetes, are at high risk for severe consequences of COVID-19[8-10]

**Current COVID-19 prevention strategies may still leave patients vulnerable[2,7,11]**

# The vulnerability to COVID-19 starts at the moment of SARS-CoV-2 exposure[12]

## SARS-CoV-2 viral load can rapidly increase after an exposure, making the period between exposure and illness a critical window to prevent COVID-19[12-16]



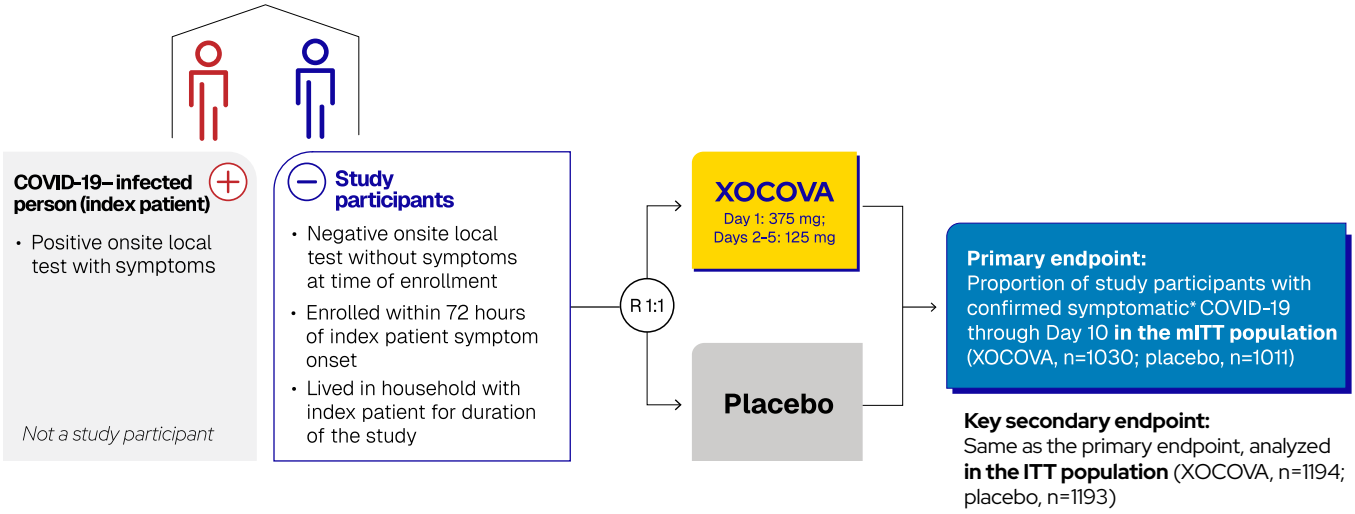

Conceptual illustration created using information from Puhach O et al. *Nat Rev Microbiol.* 2023;21(3):147-161.

**Early intervention during the incubation period is critical—within 72 hours after exposure[13,14,16]**

# SCORPIO-PEP: The first oral antiviral trial to meet the primary endpoint of preventing symptomatic* COVID-19 after exposure[1,2,17,18]

SCORPIO-PEP was a randomized, double-blind, placebo-controlled, multinational Phase 3 trial conducted in 5 countries evaluating XOCOVA in asymptomatic standard- or high-risk participants 12 years of age or older considered not to have SARS-CoV-2 infection.[1,19]

## 2387 participants were randomized 1:1 to receive either XOCOVA or placebo for 5 days, then subsequently evaluated through Day 28[1,19†]




## Baseline testing protocol (mITT vs ITT)[1]

Eligible participants tested negative for SARS-CoV-2 at a local laboratory using a rapid antigen test or RT-PCR. Samples were taken at the same time and sent to a central laboratory (RT-PCR) for confirmation. Differing test results led to 2 separate analysis populations.

**ITT population (XOCOVA, n=1194; placebo, n=1193):** Includes participants who tested negative on the local test but were subsequently found to be either negative or positive via confirmatory central RT-PCR test at baseline.

**mITT population (XOCOVA, n=1030; placebo, n=1011):** Only participants found to be negative on both the local and confirmatory central RT-PCR tests at baseline.

XOCOVA was studied in a broad range of patients. Baseline characteristics were similar in the XOCOVA and placebo groups.[1,19,20]

*Defined as central-laboratory–confirmed RT-PCR positivity of SARS-CoV-2 and ≥1 of the 14 prespecified COVID-19 symptoms lasting ≥48 hours.[19]
†Nasopharyngeal swabs were collected on Days 1, 3, 6, 10, 15, 21, and 28 for RT-PCR testing of participants taking XOCOVA or placebo.[19]

ITT=intention-to-treat; mITT=modified intention-to-treat; R=randomization; RT-PCR=reverse transcriptase polymerase chain reaction.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Embryofetal Toxicity**

Based on animal data, XOCOVA may cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential that XOCOVA may cause fetal harm. Verify pregnancy status of females of reproductive potential before initiating XOCOVA and advise using effective contraception during XOCOVA use and for 2 weeks after the final dose.

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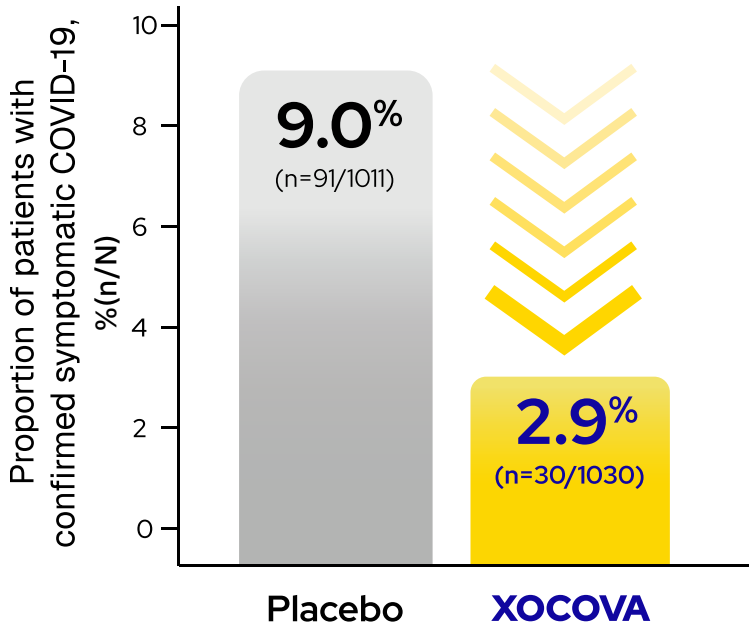
# XOCOVA significantly reduced the risk of developing symptomatic* COVID-19 after exposure through Day 10[1]

## Primary endpoint (mITT population)[1]




**67%**

**Significant risk reduction in developing symptomatic COVID-19**

Risk ratio: 0.33 (95% CI, 0.22-0.49)†
*P*<0.0001†

## Key secondary endpoint (ITT population)[1]

**57%**

**Significant risk reduction in developing symptomatic COVID-19 even when including all randomized participants**

Placebo: 10.2% (n=122/1193); XOCOVA: 4.4% (n=52/1194)
Risk ratio: 0.43 (95% CI, 0.32-0.59)†
*P*<0.0001†

*Defined as central-laboratory–confirmed RT-PCR positivity of SARS-CoV-2 and ≥1 of the 14 prespecified COVID-19 symptoms lasting ≥48 hours.[19]
†Risk ratio, 95% CI, and *P* value were calculated using a GEE Poisson regression model.[1,19-21]

GEE=generalized estimating equation.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Risk of Serious Adverse Reactions Due to Drug Interactions**
XOCOVA is a strong CYP3A inhibitor and an inhibitor of P-gp and BCRP. In patients receiving or initiating medications metabolized by CYP3A or transported by P-gp or BCRP, XOCOVA may increase plasma concentrations of those medications and may potentially lead to severe, life-threatening, or fatal events from increased exposure. CYP3A inducers may decrease concentrations of XOCOVA, leading to loss of therapeutic effect.

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# Proportion of high-risk and non–high-risk patients with confirmed symptomatic* COVID-19 through Day 10[19]

**Subgroup analysis (mITT population)**
**High risk[19]**

**76%** lower risk of symptomatic COVID-19 observed
Risk ratio: 0.24†

Proportion of patients with confirmed symptomatic COVID-19:

- XOCOVA: 2.4% (n=9/382)
- Placebo: 9.9% (n=37/374)

**Subgroup analysis (mITT population)**
**Non-high risk[19]**

**61%** lower risk of symptomatic COVID-19 observed
Risk ratio: 0.39†

Proportion of patients with confirmed symptomatic COVID-19:

- XOCOVA: 3.2% (n=21/648)
- Placebo: 8.5% (n=54/637)

**Data limitations:** All subgroup analyses were non-ranked endpoints not controlled for multiplicity; therefore, no clinical or statistical conclusions can be made, and data should be interpreted with caution.

## Some high-risk factors for severe illness in the study included[19]:

- **Obesity**
- **Diabetes mellitus**
- **Cardiovascular disease**
- **Chronic lung disease**
- **Chronic kidney disease**
- **Chronic liver disease**

Other high-risk factors for severe illness included Down syndrome, sickle-cell disease, immunocompromised conditions or treatment for immunocompromised conditions, dementia, smoking, and history of stroke or cerebrovascular disease.

*Defined as central-laboratory–confirmed RT-PCR positivity of SARS-CoV-2 and ≥1 of the 14 prespecified COVID-19 symptoms lasting ≥48 hours.[19]
†Risk ratio was calculated using a GEE Poisson regression model.[21]

## IMPORTANT SAFETY INFORMATION (cont'd)

**Risk of Serious Adverse Reactions Due to Drug Interactions (cont'd)**
Before prescribing XOCOVA, review all concomitant medications to assess potential drug-drug interactions and determine if those medications require a dose adjustment, interruption, and/or additional monitoring. Consider the benefit of XOCOVA and whether risk of potential drug-drug interactions can be managed.

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# Demonstrated safety and tolerability profile[1,19]

## SCORPIO-PEP safety profile[1]

| | XOCOVA n=1190 | Placebo n=1187 |
|---|---|---|
| **The most common AEs (regardless of causality) occurring in ≥1% of the XOCOVA group and at a greater frequency compared to placebo[1]:** | | |
| Headache | 2.9% | 2.6% |
| Diarrhea | 1.7% | 1.3% |
| Cough | 1.1% | 0.6% |
| **Discontinuation of study intervention due to AE[1]** | <0.1% | <0.1% |
| **Hospitalizations or deaths[19]** | 0 | 0 |
| **Laboratory abnormalities[1]** Asymptomatic hemoglobin declines from baseline of >2 g/dL | 3% | 1% |

**Advise pregnant women and females of reproductive potential that XOCOVA may cause fetal harm. Women should use effective contraception while taking XOCOVA and for 2 weeks after the final dose.[1]**

XOCOVA had no reports of dysgeusia (taste disturbance) in the SCORPIO-PEP trial[19,21]

### XOCOVA has a well-established drug interaction profile[1]

XOCOVA is contraindicated when administered with drugs primarily metabolized by CYP3A or with strong CYP3A inducers. Review all concomitant medications to assess potential drug-drug interactions and determine if those medications require a dose adjustment, interruption, and/or additional monitoring.[1]

The overall safety profile of XOCOVA is based on data from 2831 adults and adolescents exposed to the recommended dosage and duration of XOCOVA in multiple controlled clinical trials, including SCORPIO-PEP.[1]

**To learn more about potential drug interactions, please see Section 7 of the full Prescribing Information**

AE=adverse event.

### IMPORTANT SAFETY INFORMATION (cont'd)

**Hypersensitivity Reactions Including Anaphylaxis**
Hypersensitivity reactions, including anaphylaxis, anaphylactic shock, and angioedema have been reported. If signs and symptoms of a clinically significant hypersensitivity reaction occur, immediately discontinue XOCOVA and initiate appropriate treatment.

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# XOCOVA offers once-daily dosing: 7 tablets over a 5-day course of therapy[1]

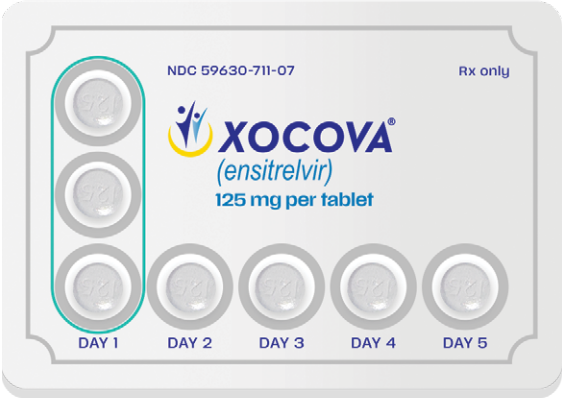
## Dosing information for XOCOVA[1]

Prompt administration of XOCOVA, within 72 hours post-exposure, is important.

Three tablets as a single dose on Day 1, then 1 tablet once daily on Days 2 through 5

Taken with or without food at approximately the same time each day

Verify pregnancy and breastfeeding status of females of reproductive potential before prescribing




For illustrative purposes.
Actual size of blister pack is approximately 5" x 3".

**Tablet image in proportion to dime**


**Dime shown for scale**

**XOCOVA is monotherapy—it does not contain ritonavir[1]**

**No dose adjustment is recommended with XOCOVA for patients with mild, moderate, or severe renal or mild or moderate hepatic impairment[1]***

*The pharmacokinetics and safety of XOCOVA have not been studied in patients with kidney failure receiving dialysis or with severe hepatic impairment (Child-Pugh Class C).[1]

### IMPORTANT SAFETY INFORMATION (cont'd)

**Lactation**

There are no data on the presence of XOCOVA in human milk, effects on breastfed infants, or effects on milk production. XOCOVA was present in the milk of lactating rats. Advise women not to breastfeed while on XOCOVA and for 2 weeks after the final dose.

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# XOCOVA can help appropriate patients be prepared in the event of a COVID-19 exposure[1]

## XOCOVA needs to be started within 3 days after exposure, but timely access may not be possible in all situations[1]

Consider prescribing XOCOVA for appropriate patients to have **on hand** in case of future COVID-19 exposure

**Important**

Advise your patients to do the following before they take XOCOVA:

1. Notify you of any changes to their medications, vitamins, or supplements to assess for potential serious drug interactions[1]
2. Verify they are not pregnant, breastfeeding, or planning to become pregnant or breastfeed[1]
3. Understand the appropriate dosing and administration of XOCOVA[1]
4. Check the expiration date on the XOCOVA blister pack
5. Contact your office if they have any questions

Keep them **PEP-ready** for their next exposure

**IMPORTANT SAFETY INFORMATION (cont'd)**

**Adverse Reactions**

The most common adverse events occurring in ≥1% of XOCOVA patients and at greater frequency than placebo, respectively, were headache (2.9% vs 2.6%), diarrhea (1.7% vs 1.3%), and cough (1.1% vs 0.6%).

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# Helpful savings for your eligible commercially insured patients

## How to get savings support for XOCOVA

- Eligible patients must have commercial insurance that provides coverage for XOCOVA. This offer is not valid for cash paying patients, patients with no insurance, or patients with state or federal health insurance, including but not limited to: Medicare, Medicare Advantage, Medicaid, VA health benefit programs, TRICARE, or the Indian Health Service
- Patients should call their pharmacy to confirm availability of XOCOVA and present their prescription
- If eligible, a $0 co-pay may be automatically applied or obtained using the XOCOVA co-pay offer information and pharmacist instructions shown here

Please see the full terms and conditions at XocovaHCP.com for more information.

*Terms and conditions apply.


Physical co-pay card not needed for offer.

## Pharmacist instructions for a patient with an eligible third-party payer:

- When you redeem this card, you certify that you have not submitted and will not submit a claim for reimbursement under any federal, state, or other government health insurance programs for this prescription
- Submit the claim to the primary third-party payer first and then submit the balance due as a Secondary Payer COB (coordination of benefits) with patient responsibility amount and a valid Other Coverage Code (e.g., 8) to BIN #637765. The patient's out-of-pocket expense will be reduced up to the maximum savings limit for the program
- Valid Other Coverage Code required. For any questions regarding online processing, please call the Help Desk at 1-877-4XOCOVA

### IMPORTANT SAFETY INFORMATION (cont'd)

**Laboratory Abnormalities**
Asymptomatic hemoglobin declines from baseline of >2 g/dL occurred in XOCOVA and placebo patients (3% vs 1%, respectively).

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# References

**1.** XOCOVA [package insert]. Florham Park, NJ: Shionogi Inc. **2.** U.S. Centers for Disease Control and Prevention. Updated February 5, 2026. Accessed May 28, 2026. https://www.cdc.gov/covid/treatment/index.html **3.** Madewell ZJ, Yang Y, Longini IM Jr, Halloran ME, Dean NE. Household secondary attack rates of SARS-CoV-2 by variant and vaccination status: an updated systematic review and meta-analysis. *JAMA Netw Open.* 2022;5(4):e229317. **4.** Baker JM, Nakayama JY, O'Hegarty M, et al. Household transmission of SARS-CoV-2 in five US jurisdictions: comparison of Delta and Omicron variants. *PLoS One.* 2025;20(1):e0313680. **5.** Sumsuzzman DM, Ye Y, Wang Z, et al. Impact of disease severity, age, sex, comorbidity, and vaccination on secondary attack rates of SARS-CoV-2: a global systematic review and meta-analysis. *BMC Infect Dis.* 2025;25(1):215. **6.** U.S. Centers for Disease Control and Prevention. Vaccination trends. Updated May 22, 2026. Accessed May 28, 2026. https://www.cdc.gov/respiratory-viruses/data/vaccination-trends.html **7.** Link-Gelles R, Chickery S, Webber A, et al. Interim estimates of 2024-2025 COVID-19 vaccine effectiveness among adults aged ≥18 — VISION and IVY networks, September 2024-January 2025. *MMWR Morb Mortal Wkly Rep.* 2025;74(6):73-82. **8.** Watson KB, Wiltz JL, Nhim K, Kaufmann RB, Thomas CW, Greenlund KJ. Trends in multiple chronic conditions among US adults, by life stage, behavioral risk factor surveillance system, 2013-2023. *Prev Chronic Dis.* 2025;22:E15. **9.** U.S. Centers for Disease Control and Prevention. People with certain medical conditions and COVID-19 risk factors. Updated June 11, 2025. Accessed May 28, 2026. https://www.cdc.gov/covid/risk-factors/index.html **10.** Ajufo E, Rao S, Navar AM, Pandey A, Ayers CR, Khera A. U.S. population at increased risk of severe illness from COVID-19. *Am J Prev Cardiol.* 2021;6:100156. **11.** U.S. Centers for Disease Control and Prevention. Staying up to date with COVID-19 vaccines. Updated November 19, 2025. Accessed May 28, 2026. https://www.cdc.gov/covid/vaccines/stay-up-to-date.html **12.** Jang S, Rhee JY, Wi YM, Jung BK. Viral kinetics of SARS-CoV-2 over the preclinical, clinical, and postclinical period. *Int J Infect Dis.* 2021;102:561-565. **13.** V'kovski P, Kratzel A, Steiner S, Stalder H, Thiel V. Coronavirus biology and replication: implications for SARS-CoV-2. *Nat Rev Microbiol.* 2021;19(3):155-170. **14.** Bhavnani D, James ER, Johnson KE, et al. SARS-CoV-2 viral load is associated with risk of transmission of household and community contacts. *BMC Infect Dis.* 2022;22(1):672. **15.** Puhach O, Meyer B, Eckerle I. SARS-CoV-2 viral load and shedding kinetics. *Nat Rev Microbiol.* 2023;21(3):147-161. **16.** Del Águila-Mejía J, Wallmann R, Calvo-Montes J, Rodríguez-Lozano J, Valle-Madrazo T, Aginagalde-Llorente A. Secondary attack rate, transmission and incubation periods, and serial interval of SARS-CoV-2 Omicron variant, Spain. *Emerg Infect Dis.* 2022;28(6):1224-1228. **17.** Hammond J, Yunis C, Fountaine RJ, et al. Oral nirmatrelvir-ritonavir as postexposure prophylaxis for Covid-19. *N Engl J Med.* 2024;391(3):224-234. **18.** Alpizar SA, Accini J, Anderson DC, et al; MOVe-AHEAD study group. Molnupiravir for intra-household prevention of COVID-19: the MOVe-AHEAD randomized, placebo-controlled trial. *J Infect.* 2023;87(5):392-402. **19.** Hayden FG, Shinkai M, Clark TW, et al. Ensitrelvir for Covid-19 postexposure prophylaxis in household contacts. *N Engl J Med.* 2026;394(19):1905-1915. **20.** Hayden FG, Shinkai M, Clark TW, et al. Ensitrelvir for Covid-19 postexposure prophylaxis in household contacts. *N Engl J Med.* 2026;394(19):1905-1915. Supplemental appendix. Accessed May 28, 2026. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2509306/suppl_file/nejmoa2509306_appendix.pdf **21.** Data on file. Shionogi Inc. Florham Park, NJ.

XOCOVA® (ensitrelvir) 125 mg tablets

# **Consider XOCOVA** for your patients 12 years and older who have been exposed to COVID-19[1]

**Explore XOCOVA for COVID-19 PEP[1] at XocovaHCP.com**

**Eligible commercially insured patients may pay $0* for XOCOVA**

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