

## PATIENT INFORMATION

**XOCOVA® (zoe koe vah)**

(ensitrelvir)

tablets, for oral use

### What is XOCOVA?

XOCOVA is a prescription medicine that is used to help prevent coronavirus disease 2019 (COVID-19) in adults and children 12 years of age and older following contact with a person who has COVID-19 (post-exposure prophylaxis). It is not known if XOCOVA is safe and effective in children less than 12 years of age.

### Do not take XOCOVA if you:

- are allergic to ensitrelvir or any of the ingredients in XOCOVA. See the end of this leaflet for a complete list of ingredients in XOCOVA. See **“What are the possible side effects of XOCOVA?”** for signs and symptoms of allergic reactions.
- take any of the following medicines, as these medicines may interact with XOCOVA and may cause severe or life-threatening side effects or death:
  - apalutamide
  - carbamazepine
  - colchicine
  - dihydroergotamine
  - enzalutamide
  - eplerenone
  - ergotamine
  - finerenone
  - ivabradine
  - lomitapide
  - lumacaftor/ivacaftor
  - lurasidone
  - methylergonovine
  - phenytoin
  - pimozone
  - quinidine
  - rifampin
  - St. John’s wort
  - simvastatin
  - triazolam
  - voclosporin

These are not the only medicines that may cause serious or life-threatening side effects if taken with XOCOVA. XOCOVA may increase or decrease the levels of many medicines in your body.

It is very important to tell your healthcare provider about all of the medicines you take because additional laboratory tests or changes in the dose of your other medicines may be necessary during treatment with XOCOVA. Your healthcare provider may tell you about specific symptoms to watch for that may indicate that you need to stop or decrease the dose of some of your other medicines.

### Before taking XOCOVA, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. XOCOVA may harm your unborn baby.
  - Females who are able to become pregnant:**
  - Your healthcare provider will check with you to see if you are pregnant before you start XOCOVA.
  - Use effective birth control (contraception) during treatment with XOCOVA and for 2 weeks after the final dose of XOCOVA.
  - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with XOCOVA.
- are breastfeeding or plan to breastfeed. It is not known if XOCOVA passes into your breastmilk. **Do not** breastfeed during treatment with XOCOVA and for 2 weeks after the final dose of XOCOVA.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. See **“Do not take XOCOVA if you:”** for a list of medicines that interact with XOCOVA.

- Your healthcare provider can tell you if it is safe to take XOCOVA with other medicines.
- You can ask your healthcare provider or pharmacist for a list of medicines that interact with XOCOVA.
- Do not start taking a new medicine without telling your healthcare provider.

### How should I take XOCOVA?

- Take XOCOVA exactly as your healthcare provider tells you to take it.
- **Take XOCOVA for 5 days. Do not** stop taking XOCOVA without talking to your healthcare provider.
- XOCOVA comes in a blister pack containing 7 tablets.
- **Do not** remove XOCOVA tablets from the blister pack until you are ready to take your dose.
- Take XOCOVA with or without food.
- Take XOCOVA at about the same time each day.
- If you miss a dose of XOCOVA, take the missed dose as soon as possible on that same day. Then return to the normal dosing schedule the next day.
- If you take too much XOCOVA, call your healthcare provider or go to the nearest hospital emergency room right away.

### How to take XOCOVA

**XOCOVA package**



**On Day 1:** Take 3 XOCOVA tablets together.



**For the next 4 days (Days 2 to 5):** Take 1 XOCOVA tablet each day.



**What are the possible side effects of XOCOVA?**

**XOCOVA may cause serious side effects, including:**

- **Allergic reactions, including severe allergic reactions (anaphylaxis).** Stop taking XOCOVA and get medical help right away if you get any of the following symptoms of an allergic reaction:
  - skin rash, hives
  - itching
  - swelling of the mouth, lips, tongue, or face
  - trouble swallowing or breathing
  - throat tightness
  - dizziness or feeling lightheaded
  - stomach-area (abdomen) pain
  - vomiting

**The most common side effects of XOCOVA include:**

- headache
- diarrhea
- cough

These are not all of the possible side effects of XOCOVA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store XOCOVA?**

- Store XOCOVA at room temperature between 68°F to 77°F (20°C to 25°C).
- Store XOCOVA in the original package.

**Keep XOCOVA and all medicines out of the reach of children.**

**General information about the safe and effective use of XOCOVA.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XOCOVA for a condition for which it was not prescribed. Do not give XOCOVA to other people. It may harm them. You can ask your pharmacist or healthcare provider for information about XOCOVA that is written for healthcare professionals.

**What are the ingredients in XOCOVA?**

**Active ingredient:** ensitrelvir

**Inactive ingredients:** colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, mannitol, microcrystalline cellulose, and magnesium stearate.

**Manufactured for:** Shionogi Inc., Florham Park, NJ 07932

© Shionogi Inc.

20xx

For more information, go to [www.shionogi.com](http://www.shionogi.com) or call 1-800-849-9707.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 05/2026