Xocova – Availability of Product

This medical response contains information in addition to that provided in the XOCOVA® (ensitrelvir) tablets, for oral use Full Prescribing Information approved by the U.S. Food and Drug Administration (FDA). Shionogi does not recommend the use of XOCOVA in any manner other than as described in the Full Prescribing Information. **Please read the attached Xocova Full Prescribing Information**, including the Patient Information leaflet.

The Patient Information leaflet summarizes important information about XOCOVA. You should read the Patient Information leaflet before you start using XOCOVA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

AVAILABILITY

XOCOVA is available for retail pharmacies to order. A prescription from a healthcare provider is required before XOCOVA can be dispensed. Patients should consult their healthcare provider to determine whether XOCOVA is appropriate for them. Once prescribed, XOCOVA may be available through participating retail pharmacies. Because availability may vary, patients should contact their local pharmacy for the most current availability information.

For more information, or if you have questions about your medical condition or treatment, please talk to your healthcare provider or pharmacist.

RELEVANT XOCOVA PATIENT INFORMATION

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.[1]

Do not take XOCOVA if you[1]:

• are allergic to ensitrelvir or any of the ingredients in XOCOVA.
• 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	○ finerenone	○ pimozide
○ carbamazepine	○ ivabradine	○ quinidine
○ colchicine	○ lomitapide	○ rifampin
○ dihydroergotamine	○ lumacaftor/ivacaftor	○ St. John's wort
○ enzalutamide	○ lurasidone	○ simvastatin
○ eplerenone	○ methylergonovine	○ triazolam
○ ergotamine	○ phenytoin	○ 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.[1]

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.[1]

Please read the attached XOCOVA **Full Prescribing Information, including the Patient Information leaflet.** The use of XOCOVA in any manner other than as described in the Full Prescribing Information approved by the FDA is not recommended.

The XOCOVA Full Prescribing Information is intended for use by healthcare providers and may or may not contain information pertinent to your specific situation. If you have questions, please contact your doctor or pharmacist. Your doctor or pharmacist is more familiar with your past and present medical history and can place the enclosed information in an appropriate perspective for you. If your doctor or pharmacist has any specific questions about XOCOVA, please have them contact us directly.

REFERENCE

1. XOCOVA® (ensitrelvir) tablets, for oral use [Prescribing Information]. Shionogi Inc.

ENCLOSURES
XOCOVA® (ensitrelvir) tablets, for oral use [Prescribing Information]. Shionogi Inc.
XOCOVA® (ensitrelvir) tablets, for oral use [Patient Information]. Shionogi Inc.