Xocova – Storage, Stability, and Shelf Life

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.**

1. RECOMMENDED STORAGE

Store XOCOVA (ensitrelvir) in the original package at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].[1]

2. SHELF LIFE

XOCOVA tablets have a shelf life of approximately 36 months from the date of manufacture when stored at 20°C to 25°C (68°F to 77°F). All XOCOVA packages are labeled with an expiration date. XOCOVA is safe and effective when stored and used according to the product labeling.[2]

3. RELEVANT PRESCRIBING INFORMATION

Indications and Usage

XOCOVA is indicated for post-exposure prophylaxis 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.[1]

Contraindications

XOCOVA is contraindicated in patients with a history of clinically significant hypersensitivity reactions to ensitrelvir or any other components of the product.[1]

XOCOVA is contraindicated in patients taking drugs that are:

- Primarily metabolized by CYP3A for which elevated concentrations may be associated with serious and/or life-threatening reactions and
- Strong CYP3A inducers because they may significantly reduce ensitrelvir plasma concentrations, leading to the potential loss of virologic response.[1]

Please read the attached XOCOVA **Full Prescribing Information**. The use of XOCOVA in any manner other than as described in the Full Prescribing Information approved by the U.S. Food and Drug Administration (FDA) is not recommended.

ABBREVIATIONS
COVID-19: coronavirus disease
CYP3A: Cytochrome P450, family 3, subfamily A

REFERENCES
1. XOCOVA® (ensitrelvir) tablets, for oral use [Prescribing Information]. Shionogi Inc.
2. Ensitrelvir Data on File 27. Shionogi Inc.

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