Xocova – Gluten Content

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). This document is being provided in response to an unsolicited request for medical information from a healthcare professional. 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.**

ACTIVE INGREDIENT

XOCOVA oral tablets contain 125 mg of ensitrelvir.[1]

INACTIVE INGREDIENTS

XOCOVA oral tablets contain these inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, mannitol, microcrystalline cellulose, and magnesium stearate.[1]

GLUTEN CONTENT

XOCOVA contains mannitol, an inactive ingredient that is manufactured from maize starch and/or wheat starch that contains trace amounts of gluten (<20 parts per million).[2] Prescribers should exercise clinical judgment and consider this information when prescribing XOCOVA to patients with gluten sensitivities.

XOCOVA does not contain barley, rye, or oats. However, we cannot guarantee the absence of trace amounts of barley, rye, or oats due to the manufacturing process. Barley, rye, and oats were present at the plant site, and the equipment used to manufacture ensitrelvir was also used for other products that contain barley, rye, and oats.[2]

XOCOVA does not contain spelt. Spelt was not present at the plant site, and the equipment used to manufacture ensitrelvir was not used for other products that contain spelt.[2]

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:[1]

- 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.

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.

REFERENCES

1. XOCOVA® (ensitrelvir) tablets, for oral use [Prescribing Information]. Shionogi Inc.
2. Ensitrelvir Data on File 11. Shionogi Inc.

ENCLOSURE

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