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Summary of Investigation Results

Ensitrelvir fumaric acid

July 20, 2023

Non-proprietary name

Ensitrelvir fumaric acid

Brand name (marketing authorization holder)

Xocova Tablets 125 mg (Shionogi & Co., Ltd.)

Japanese market launch

November 2022

Indications

Treatment of disease caused by SARS-CoV-2 infection (COVID-19)

Summary of revisions

“Anaphylaxis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving anaphylaxis reported in Japan were evaluated. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA considered as follows: The number of cases for which a causal relationship to ensitrelvir fumaric acid was reasonably possible is one.; nonetheless, since occurrence of anaphylaxis due to ensitrelvir fumaric acid, which is foreign to the human body, is an obvious potential risk and this drug is an emergency approval product, it is important to take safety measures without delay. Therefore, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary before further cases are reported.

Pharmaceuticals and Medical Devices Agency

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Reference: Number of cases* and patient mortalities involving anaphylaxis reported in Japan

A total of 3 cases have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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