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Summary of Investigation Results

Molnupiravir

June 14, 2022

Non-proprietary name

Molnupiravir

Brand name (Marketing authorization holder)

Lagevrio Capsules 200 mg (MSD K.K.)

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 and overseas were evaluated. Cases for which a causal relationship between molnupiravir and anaphylaxis was reasonably possible have been reported in Japan and overseas. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

Number of cases and patient mortalities of anaphylaxis reported in Japan and overseas during the previous 3 fiscal years

A total of 8 cases have been reported in Japan to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).
A total of 4 patient mortalities have been reported to date. (A causal relationship between the drug and death subsequent to the event could not be established for any of these cases.)
(Japanese market launch: December 2021)

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A total of 11 cases have been reported overseas to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).
A total of 2 patient mortalities have been reported to date. (A causal relationship between the drug and death subsequent to the event could not be established for any of these cases.)

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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