

Pharmaceuticals and Medical Devices Agency



No.16 December 2024

Administration of Treatment Drugs for COVID-19 (Xocova Tablets and Lagevrio Capsules) to Women of Childbearing Potential

- The administration of treatment drugs for COVID-19, "ensitrelvir fumaric acid" (Xocova Tablets) and "molnupiravir" (Lagevrio Capsules) to pregnant women or women who may be pregnant is contraindicated since the drugs have a risk of teratogenicity.
- However, cases have been intermittently reported in which pregnancy was detected after administration of each drug.
- When administering Xocova Tablets or Lagevrio Capsules, the following precautions should be checked. In addition, healthcare professionals are encouraged to use the "Preliminary Checklist for Administering the Drug" (Risk Management Plan (RMP) materials for healthcare professionals) and "Materials for Female Patients Prescribed the Drug and Their Family Members" (RMP materials for patients), which are disseminated by the marketing authorization holders (MAHs).

Precautions prior to administering the drugs to women of childbearing potential

<u>The necessity of administering the drugs</u> to women of childbearing potential <u>should be carefully considered</u>. If administration is deemed necessary, attention should be paid to the following points:

- Prior to administering these drugs, the absence of pregnancy and the absence of the possibility of pregnancy should be confirmed through sufficient patient interviews.
- The following should be explained to patients before starting administration of these drugs:
 - These drugs can cause foetal harm when administered to a pregnant woman.
 - If pregnancy is detected or suspected during administration of these drugs, these drugs should be discontinued immediately.
 - If pregnancy is detected or suspected during administration of these drugs or within 2 weeks for Xocova Tablets or within 4 days for Lagevrio Capsules after the last administration of these drugs, a physician, pharmacist, etc. should be consulted promptly.

PMDA Alert for Proper Use of Drugs https://www.pmda.go.jp/

Reports of cases

The MAHs have reported the following number of cases in which pregnancy was detected after administering these drugs (by fiscal year and cumulative data).

<Xocova Tablets>

Cumulative number of the cases: 54 (receipt of information: From November 22, 2022 to October 31, 2024)

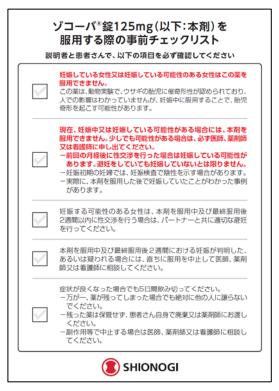
Fiscal Year (receipt of information)	FY 2021	FY 2022	FY 2023	FY 2024
Number of cases		3	34	17

<Lagevrio Capsules>

Cumulative number of the cases: 19 (receipt of information: From December 24, 2021 to October 31, 2024)

Fiscal Year (receipt of information)	FY 2021	FY 2022	FY 2023	FY 2024
Number of cases	1	2	14	2

Please refer to the information search page of prescription drugs in the PMDA website (<u>https://www.pmda.go.jp/PmdaSearch/iyakuSearch/</u> (only in Japanese)) for the "Preliminary Checklist for Administering the Drug" and "Materials for Female Patients Prescribed the Drug and Their Family Members."





About this information

*PMDA Alert for Proper Use of Drugs communicates to healthcare professionals with clear information from the perspective of promoting the proper use of drugs. The information presented here includes such cases where the reporting frequencies of similar reports have not decreased despite relevant alerts provided in package inserts, among adverse drug reaction/infection cases reported in accordance with the PMD Act.

*We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future

*This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided to promote the proper use of the drugs.

*This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

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Published and translated by the Pharmaceuticals and Medical Devices Agency

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Access to the most up-to-date safety information is available via the PMDA medi-navi. (only in Japanese)



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