独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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.

Summary of Investigation Results

Nirmatrelvir/ritonavir
Enzalutamide

April 8, 2025

Non-proprietary name

a. Nirmatrelvir/ritonavir

b. Enzalutamide

Brand name (marketing authorization holder)

a. Paxlovid Pack, Paxlovid Pack 300, 600 (Pfizer Japan Inc.)

b. Xtandi Tablets 40 mg, 80 mg (Astellas Pharma Inc.)

Japanese market launch

a. Paxlovid Pack, Paxlovid Pack 600: February 2022, Paxlovid Pack 300: March 2023

b. May 2014 (market launch of Xtandi Capsules 40 mg)

Indications

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

b. •Castration-resistant prostate cancer
•Metastatic prostate cancer

Summary of revisions

a.

1. “Patients receiving the following drugs: Enzalutamide” should be added to 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.).
2. “Enzalutamide” should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

b.

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1. “Patients receiving nirmatrelvir/ritonavir” should be added to 2. CONTRAINDICATIONS. (This drug is contraindicated to the following patients.).
2. “Nirmatrelvir/ritonavir” should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

Investigation results and background of the revision

Pharmacokinetic effects regarding the co-administration of nirmatrelvir/ritonavir and enzalutamide were evaluated. Co-administration of nirmatrelvir/ritonavir and enzalutamide may lead to a decrease in the blood concentration of nirmatrelvir and ritonavir, causing a disappearance of antiviral activity as well as the occurrence of resistance. As a result of consultation with expert advisors, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Of note, opinions regarding the impacts of contraindicating co-administration of nirmatrelvir/ritonavir and enzalutamide on clinical settings were sought from relevant academic societies, confirming no specific major problems.

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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