

Safety Alert

May 2025

Nirmatrelvir/Ritonavir -new contraindication: co-administration with enzalutamide

EDA performs label update to include the following:

Contraindications:

Co-administration with enzalutamide

Background:

Therapeutic Indication:

Nirmatrelvir/Ritonavir

Nirmatrelvir/Ritonavir is indicated for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19.

Enzalutamide

- is indicated as monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy
- in combination with androgen deprivation therapy for the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) .
- for the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC)
- for the treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically.
- for the treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.

References:

EMA ([Click here](#))