

Safety Alert

May 2024

Nirmatrelvir & Ritonavir – Contraindications with Medicinal products that are highly dependent on CYP3A for clearance leadin to serious and/or life-threatening reactions

EDA performs label update to include the following:

4 CLINICAL PARTICULARS

4.3 Contraindications

Table : Medicinal products that are contraindicated for concomitant use with nirmatrelvir/ritonavir

<i>Medicinal product class</i>	<i>Medicinal products within class</i>	<i>Clinical comments</i>
<i>Interactions that result in increased concentrations of concomitant medicinal product as Paxlovid inhibits their CYP3A4 metabolic pathway</i>		
<i>Cardiovascular agents</i>	<i>eplerenone</i>	<i>Increased plasma concentrations of cardiovascular agents.</i>
<i>Migraine medications</i>	<i>eletriptan</i>	<i>Increased plasma concentrations of migraine medications.</i>
<i>Opioid antagonists</i>	<i>naloxegol</i>	<i>Increased plasma concentrations of opioid antagonist</i>
<i>Vasopressin receptor antagonists</i>	<i>tolvaptan</i>	<i>Increased plasma concentrations of vasopressin receptor antagonist.</i>
<i>Interactions that result in decreased concentrations of nirmatrelvir/ritonavir as the concomitant medicinal products induce Paxlovid's CYP3A4 metabolic pathway</i>		
<i>Anticonvulsants</i>	<i>primidone</i>	<i>Decreased plasma concentrations of nirmatrelvir/ritonavir may lead to loss of virologic response and possible resistance</i>

Background:

Therapeutic Indication

Nirmatrelvir & Ritonavir is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19

References:

MHRA ([Click here](#))