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US FDA approves first oral anti-viral for treatment of COVID-19 in adults

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Paxlovid remains an important treatment option for people at high risk for progression to severe COVID-19, including those with prior immunity

The US Food and Drug Administration (FDA) has approved the oral anti-viral Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalisation or death. Paxlovid is the fourth drug, and first oral anti-viral pill, approved by the FDA to treat COVID-19 in adults.

Paxlovid manufactured and packaged under the emergency use authorisation (EUA) and distributed by the U.S. Department of Health and Human Services will continue to be available to ensure continued access for adults, as well as treatment of eligible children ages 12-18 who are not covered by today's approval. Paxlovid is not approved or authorised for use as a pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

The efficacy of Paxlovid was primarily supported by the final results of the EPIC-HR clinical trial. EPIC-HR was a randomised, double-blind, placebo-controlled clinical trial studying Paxlovid for the treatment of non-hospitalised symptomatic adults with a laboratory confirmed diagnosis of SARS-CoV-2 infection.

The most common side effects of taking Paxlovid include impaired sense of taste and diarrhoea. Patients should discuss with their health care provider whether Paxlovid is right for them.

Nirmatrelvir/ritonavir, sold under the brand name Paxlovid, is a co-packaged oral medication, developed by the American pharmaceutical firm Pfizer.