23 July 2026
EMADOC-1829012207-58529
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zokovea

ensitrelvir

On 23 July 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zokovea, intended for the post-exposure prophylaxis of COVID-19.

The applicant for this medicinal product is Shionogi B.V.

Zokovea will be available as 125 mg tablets. The active substance of Zokovea is ensitrelvir, an antiviral for systemic use (ATC code: J05AE16), which acts through selective inhibition of the SARS-CoV-2 3C-like protease, thereby inhibiting viral replication.

The benefit of Zokovea is a reduced risk of symptomatic COVID-19 in household contacts of an individual with COVID-19 when administered within 72 hours after index patient symptom onset, as observed in a multicentre, double-blind, randomised, placebo-controlled study evaluating efficacy and safety.

The most common side effects are hypertriglyceridaemia, headache, diarrhoea and nausea.

The full indication is:

> Zokovea is indicated for the post-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older. Zokovea should be used in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union