FDA approves Pfizer pill as first at-home COVID-19 treatment

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(HealthDay)—The U.S. Food and Drug Administration on Wednesday

approved the emergency use of the new Pfizer antiviral pill Paxlovid in people who are at high risk for severe COVID-19. It is the first approved treatment for COVID-19 meant to be taken at home.

"Today's authorization introduces the first treatment for COVID-19 that is in the form of a pill that is taken orally—a major step forward in the fight against this global pandemic," Patrizia Cavazzoni, M.D., director of the FDA Center for Drug Evaluation and Research, said in an agency news release. "This authorization provides a new tool to combat COVID-19 at a crucial time in the pandemic as new variants emerge."

Pfizer first asked for emergency authorization in mid-November, and later announced stunning final trial results on the power of Paxlovid to guard against severe COVID-19. In that trial, the pill, taken for five days, slashed the odds for hospitalization and death by nearly 90 percent in high-risk people. Paxlovid should be taken within three to five days of symptom onset, the FDA said.

Paxlovid is a combination of ritonavir and a new molecule developed specifically to disable severe acute respiratory syndrome coronavirus 2. The drug does have some limitations. Ritonavir can interact with many commonly taken medicines, and those risks may need to be managed by physicians and pharmacists, the FDA said.

Possible side effects of Paxlovid include impaired sense of taste, diarrhea, high blood pressure, and muscle aches, the FDA said. Using Paxlovid in people with uncontrolled or undiagnosed HIV infection may trigger HIV-1 drug resistance. Ritonavir can cause liver damage, so caution should be used when giving Paxlovid to patients with liver conditions, the agency added. Paxlovid is also not recommended in patients with severe kidney impairment. In patients with moderate kidney impairment, a reduced Paxlovid dose is needed, the FDA said.

More information: More Information