

FDA approves treatments for heart failure caused by rare disease

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(HealthDay)—Vyndaqel (tafamidis meglumine) and Vyndamax

(tafamidis) capsules have been approved to treat adults with cardiomyopathy caused by transthyretin mediated amyloidosis (ATTR-CM), the U.S. Food and Drug Administration announced today.

Recommended dosage is four 20-mg capsules of Vyndaqel once daily or a single 61-mg capsule of Vyndamax once daily, according to the manufacturer. The two drugs, which are the first approved treatment for ATTR-CM, have the same moiety of tafamidis but are not substitutable on a per-milligram basis, the FDA said.

Approval was based on a clinical trial of 441 patients with ATTR-CM who were randomly assigned to receive Vyndaqel or placebo. Patients receiving Vyndaqel had a higher survival rate at an average of 30 months and a reduction in cardiovascular-related hospitalizations compared with [patients](#) receiving placebo.

Although patient numbers in the [clinical trials](#) were small, researchers did not identify any drug-related side effects. The manufacturer's prescribing information for Vyndaqel lists potential side effects of diarrhea, [urinary tract infection](#), vaginal infection, and abdominal pain. Because of the risk for fetal harm with tafamidis, the FDA recommends providers discuss pregnancy planning and prevention with women.

Approval was granted to FoldRx, a subsidiary of Pfizer.

More information: [More Information](#)

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