Generic Name:
Tafamidis meglumine, tafamidis
Trade Name:
Vyndaqel, Vyndamax
Company:
FoldRx
Notes:

FDA approved tafamidis meglumine and tafamidis capsules for treatment of heart disease caused by transthyretin mediated amyloidosis (ATTR-CM) in adults. These are the first FDA-approved treatments for ATTR-CM. Although both treatments have the same active moiety, tafamidis, they are not substitutable on a milligram to milligram basis, and their recommended doses differ.

Efficacy of tafamidis meglumine and tafamidis in treating ATTR-CM was shown in a clinical trial of 441 patients randomized to receive tafamidis meglumine or a placebo. After an average of 30 months, the survival rate was higher in the tafamidis meglumine group than in the placebo group was also shown to reduce the number of hospitalizations for cardiovascular problems.

The number of patients in clinical studies was small, but no drug-associated adverse effects have been identified. Tafamidis may cause fetal harm when administered to a pregnant woman. Women taking either treatment should discuss pregnancy planning and prevention with their health professional.

ATTR is caused by the buildup of abnormal deposits of specific proteins known as amyloid in the body's organs and tissues, interfering with their normal functioning. These protein deposits most frequently occur in the heart and the peripheral nervous system. Heart involvement can result in shortness of breath, fatigue, heart failure, loss of consciousness, abnormal heart rhythms and death. Involvement of the peripheral nervous system can result in a loss of sensation, pain, or immobility in the arms, legs, hands and feet. Amyloid deposits can also affect the kidneys, eyes, GI tract, and central nervous system.

Medication Monitor Categories:
New Drug Approvals