Vyndaqel (tafamidis meglumine)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Vyndaqel
- **Generic name:** Tafamidis meglumine
- **Pharmacological class:** Transthyretin (TTR) stabilizer
- **Strength and Formulation:** 20mg; soft gelatin capsules
- **Manufacturer:** Pfizer
- **How supplied:** Blister packs—120 total capsules
- **Legal Classification:** Rx

Vyndaqel


NOT FOR INDIVIDUAL RESALE
Vyndaqel® 20 mg per capsule*
(tafamidis meglumine) capsules
Attention Pharmacist: Vyndaqel is NOT substitutable on a per mg basis with other tafamidis products.
NOT FOR INDIVIDUAL RESALE
Pfizer
Contains: A total of 30 capsules per carton. Each carton contains 3 blister cards. Each blister card contains 10 capsules.
Rx only
Vyndaqel® 20 mg per capsule*
NDC 0069-1975-40
(tafamidis meglumine) capsules
Attention Pharmacist: Vyndaqel is NOT substitutable on a per mg basis with other tafamidis products.
Pfizer
Contains: A total of 120 capsules per carton. Each carton contains 4 intermediary cartons. Each intermediary carton contains 3 blister cards. Each blister card contains 10 capsules.
Rx only
Vyndaqel® 20 mg per capsule*
(tafamidis meglumine) capsules

Indication

- For the treatment of **cardiomyopathy** of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization

Dosage & Administration

- Swallow whole
- 80mg once daily
- Not substitutable with Vyndamax on a per mg basis

Considerations for Special Populations

- **Pregnancy:** Based on findings from animal studies, **may cause fetal harm** when administered to a pregnant woman; consider pregnancy planning and prevention for females of reproductive potential
- **Nursing mothers:** Based on findings from animal studies which suggest the potential for serious adverse reactions in the breastfed infant, advise patients that **breastfeeding is not recommended** during treatment
- **Pediatric:** not established
- **Geriatric:** no dosage adjustment required

Interactions

- May potentiate BCRP substrates (eg, methotrexate, rosuvastatin, imatinib)

Mechanism of Action

- Tafamidis is a selective stabilizer of transthyretin (TTR)
- Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, the rate-limiting step in the amyloidogenic process

Clinical Trials

- The efficacy of Vyndaqel was demonstrated in a multicenter, international, randomized, double-blind, placebo-controlled study in 441 patients with wild type or hereditary ATTR-CM

- Patients were randomized in a 1:2:2 ratio to receive Vyndaqel 20mg (n=88), Vyndaqel 80mg (n=176), or matching placebo (n=177) once daily for 30 months, in addition to standard of care (eg, diuretics)

Clinical Trials

- The primary end point of the study was the hierarchical combination of all-cause mortality and frequency of cardiovascular-related hospitalizations, which was defined as the number of times a patient was hospitalized for cardiovascular-related morbidity

- Results showed a significant reduction (*P* =.0006) in all-cause mortality and frequency of cardiovascular-related hospitalizations in the pooled Vyndaqel 20mg and 80mg groups vs placebo

Clinical Trials

- An analysis of individual components showed a 30% relative reduction in the risk of death when compared with placebo (hazard ratio [HR] 0.70, 95% CI: 0.51, 0.96; *P* =.026)

- There were significantly fewer cardiovascular-related hospitalizations with Vyndaqel compared with placebo with a reduction in risk of 32% corresponding to a relative risk ratio of 0.68

Clinical Trials

- A significant treatment effect was observed with Vyndaqel at 6 months and remained consistent through 30 months on both the 6-Minute Walk Test (6MWT) and the Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score, used to assess functional capacity and health status, respectively

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/vyndaqel/