Vyndaqel® ▼(tafamidis) Important Risk Minimisation Information for Health Professionals

PP-VYN-IRL-0278 Date of Preparation: November 2024

Pfizer

Important Risk Minimisation Information for Health Professionals

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Healthcare professionals are asked to report any suspected adverse reactions via Health Products Regulatory Authority (HPRA). Website: www.hpra.ie. When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates. Any suspected adverse reactions with Vyndaqel (Tafamidis) may also be reported to Pfizer Medical Information on 1800 633 363.

Background Summary

The purpose of this HCP Guide is to highlight the importance of strongly advising women to avoid pregnancy or breastfeeding while receiving Vyndaqel, to encourage you to report adverse events and any pregnancies in female patients taking Vyndaqel, to collect long term exposure data and confirming the diagnosis of ATTR-CM before prescribing Vyndaqel, to avoid administration to non-qualifying patients.

Key messages to Healthcare Professionals

- Please check that patients meet all clinical criteria for the diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) before prescribing Vyndaqel 61 mg soft capsules, to avoid administration to non-qualifying patients (see criteria section below).
- Please advise your patients on the risks associated with Vyndaqel therapy, in particular that tafamidis is not recommended during pregnancy or during lactation, and strongly encourage patient education around appropriate precautions when using Vyndaqel, particularly to avoid pregnancy by proper use of a highly effective method of contraception.
- Please advise your patients to report to you/the treating physician immediately in case of exposure to tafamidis during (or within 1 month prior to) pregnancy for the physician's reporting and assessment. Reports of exposure during pregnancy can be reported to Pfizer and participation in the Tafamidis Enhanced Surveillance Pregnancy Outcomes (TESPO) programme, designed to collect additional data on pregnancy outcome, neonate/infant status at birth and 12-month follow-up on infant milestones reached, is encouraged.
- Please advise your patients to contact you/the treating physician immediately in case of any adverse events while taking Vyndaqel, or to report adverse events directly via the national reporting system listed in the patient leaflet.
- Physicians (prescribers) and pharmacists are reminded to report promptly any suspected adverse events related to Vyndaqel to the HPRA at www.hpra.ie or to Pfizer on 1800 633 363.

Avoidance of Pregnancy

Vyndaqel is not recommended for use during pregnancy or in women of childbearing potential who are not using effective methods of contraception. This is because there are limited human pregnancy data and developmental toxicity studies in animals have shown abnormalities. Contraceptive measures should be used by women of childbearing potential during treatment with Vyndaqel and, due to its prolonged half-life, for 1 month after stopping Vyndaqel.

TESPO

Tafamidis Enhanced Surveillance Pregnancy Outcomes

TESPO is a programme to collect safety data, including major birth defects or other developmental abnormalities in live born infants, in female patients with ATTR amyloidosis who are exposed to Vyndaqel during or within 1 month prior to their pregnancy.

Although patients receiving Vyndaqel are advised to avoid pregnancy and to use highly effective methods of contraception, it is recognised that pregnancies may occur, and that the disease can present during the reproductive years in many ATTR-PN female patients and few ATTR-CM female patients.

Healthcare Professionals caring for patients who become pregnant during or within 1 month of exposure to Vyndaqel are asked to report the pregnancy to their local Pfizer office (see below for contact information). Basic pregnancy information including due dates and dates of tafamidis exposure will be collected using the Exposure During Pregnancy (EDP) form, follow-up data on the pregnancy outcome will be gathered at the female patient estimated time of delivery and information will be collected on the TESPO 12-Month Infant Follow-up Form (first-year survival, age-appropriate milestones, congenital malformations, genetic abnormalities, hospitalisation and major illnesses, vaccinations).

Clinical criteria for the diagnosis of ATTR-CM

Clinical criteria for the diagnosis of ATTR-CM patients is described in Section 4.2 of the Vyndaqel 61 mg SmPC: Treatment should be initiated under the supervision of a physician knowledgeable in the management of patients with amyloidosis or cardiomyopathy.

When there is a suspicion in patients presenting with specific medical history or signs of heart failure or cardiomyopathy, aetiologic diagnosis must be done by a physician knowledgeable in the management of amyloidosis or cardiomyopathy to confirm mATTR-CM and exclude AL [immunoglobulin light chain] amyloidosis before starting tafamidis, using appropriate assessment tools such as: bone scintigraphy and blood/urine assessment, and/or histological assessment by biopsy, and TTR genotyping to characterise as wild type or hereditary.

Thank you in advance for your support of these programmes. If you have any questions or concerns, please don't hesitate to contact Pfizer Medical Information on 1800 633 363.

If you wish to make a medical information inquiry or report an adverse event please contact Pfizer on 1800633363 or email Pfizer at medicalinformation@pfizer.com or visit www.PfizerMedicalInformation.ie.