Vyndaqel (tafamidis) - Healthcare Professional Guide

▼ 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. See section 4.8 of the SmPC for how to report adverse reactions.

IMPORTANT INFORMATION ABOUT VYNDAQEL® (TAFAMIDIS)

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, to avoid administration to non-qualifying patients (see criteria section below).

- Please advise your patients on the important potential risks associated with Vyndaqel therapy - tafamidis is not recommended during pregnancy or breastfeeding, 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 report to Pfizer all cases of female patients becoming pregnant while receiving Vyndaqel and encourage them to join 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.

- 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 via the national reporting system listed in the SmPC or to Pfizer.

Background Summary

Vyndaqel® (tafamidis meglumine) 20 mg soft capsules was approved under exceptional circumstances on 16 November 2011 by the European Commission "for the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment".

On 17 February 2020, the European Commission approved Vyndaqel® (tafamidis) 61 mg soft capsules "for the treatment of transthyretin amyloidosis in adult patients with wild-type or hereditary cardiomyopathy".

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, and confirming the diagnosis of ATTR-CM before prescribing Vyndaqel, to avoid administration to non-qualifying patients.

Avoidance of Pregnancy

Vyndaqel is not recommended for use during pregnancy/breastfeeding 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 one 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 transthyretin amyloid polyneuropathy (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 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).

Your participation in TESPO is voluntary.Information gathered from TESPO will be used to support pharmacovigilance and risk management activities to support patient safety related to Vyndaqel use in the post-marketing setting.

Clinical criteria for the diagnosis of ATTR-CM

Clinical criteria for the diagnosis of ATTR-CM patients are 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, etiologic diagnosis must be done by a physician knowledgeable in the management of amyloidosis or cardiomyopathy to confirm ATTR-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.

Call for reporting

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000

E: postlicensing.medicinesauthority@gov.mt

Alternatively, you may also report such events promptly to Pfizer at Pfizer Hellas S.A., 243 Messoghion Ave. N.Psychiko, Athens GR-15451, Greece. Pfizer Hellas Pharmacovigilance Department contact details: +30 210 67 85 908 and +30 210 67 85 808 (24hour line), fax: +30 210 81 99 096, or via the webportal Pfizer's Adverse Event Reporting Portal (pfizersafetyreporting.com). Healthcare professionals should report adverse events or reactions by brand name and batch number.