File Name	Vyndamax-SoftCap-61mg-PIL-ENG-D11		
Product	Vyndamax	**Job No.**	SO21000906
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Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Vyndamax®
Soft capsules

Each soft capsule contains: tafamidis 61 mg

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours. The medicine is not intended for children and adolescents.

1. WHAT IS THIS MEDICINE INTENDED FOR?

VYNDAMAX® is indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

Therapeutic group: A selective stabilizer of the transthyretin protein.

Transthyretin amyloid cardiomyopathy is caused by instability of the transthyretin protein (TTR), which transports various substances, such as hormones, through the body.

In patients with this disease, the protein undergoes degradation and may form amyloid fibres. The amyloid can build up between cells in the heart. Build up of amyloid in the heart prevents normal heart functioning. Vyndamax® stabilizes the protein, thus inhibiting its degradation and formation of amyloid.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see details in section 6).

Special warnings regarding use of the medicine
Consult your doctor, pharmacist or nurse before starting treatment with the medicine.

- Women of childbearing age should use contraceptives while taking the medicine and should continue using contraceptives for up to one month after stopping treatment. There is no information about use of the medicine during pregnancy.

Children and adolescents
Children and adolescents do not present with symptoms of transthyretin amyloid cardiomyopathy. The medicine is not intended for use in children and adolescents under age of 18.

Drug interactions
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
Particularly, tell your doctor or pharmacist if you are taking any of the following:

- non-steroidal anti-inflammatory drugs (NSAIDs)
- diuretic medicines (e.g. furosemide, bumetanide)
- anti-cancer medicines (e.g. methotrexate, imatinib)
- statins (e.g. rosuvastatin)
- anti-viral medicines (e.g. oseltamivir, tenofovir, ganciclovir, adefovir, cidofovir, lamivudine, zidovudine, zalcitabine)

Using this medicine and food
The capsule may be taken with or without food.

Pregnancy, breastfeeding and fertility
Do not use the medicine without consulting your doctor before starting treatment if you are pregnant, think you are pregnant, plan to become pregnant or are breastfeeding.
Women of childbearing age who are able to become pregnant must use contraceptives during treatment and for one month after stopping treatment.

Driving and using machines
Vyndamax® has no or negligible influence on the ability to drive or use machines.

Important information about some of this medicine's ingredients
This medicine contains no more than 44 mg sorbitol in each capsule. Sorbitol is a source of fructose.

If you know that you have an intolerance to certain sugar type, contact your doctor before taking the medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only.
The standard dosage is usually: one capsule (61 mg) per day, with or without food.
Swallow the capsule whole, do not split. Do not open the capsule and spread its content.

Do not replace the medicine with a medicine containing tafamidis meglumine, unless instructed by your doctor.

If you vomit shortly after taking the capsule and can identify the capsule in the gastric content, take an additional capsule on the same day (if the condition of your gastrointestinal system enables this). If you do not observe the presence of the capsule, do not take an additional dose and continue taking the medicine on the next day as scheduled.

Do not exceed the recommended dose.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember. Take the next dose at the usual time and consult your doctor. Never take a double dose to compensate for a forgotten dose!

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.
Stopping the treatment may cause progression of the disease.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of the medicine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Clinical studies have demonstrated that the side effects which occurred in patients treated with Vyndamax® were similar to the side effects which occurred in the placebo group.

Flatulence and increase in liver function blood test were reported more often in patients treated with the medicine.

You can report side effects to the Ministry of Health by following the link‘ Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
Storage conditions:
Store below 25˚C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
Polyethylene glycol 400, gelatin, glycerine, sorbitol, polysorbate 20, povidone (K-value 90), iron oxide (red), butylated hydroxytoluene, purified water

Each soft capsule contains: no more than 44 mg sorbitol

What the medicine looks like and contents of the pack:

A soft, opaque, red-brown capsule, with “VYN 61” imprinted in white.

The pack contains 3 blisters of 10 soft capsules each, overall including 30 soft capsules per pack.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 166-51-36151-00

Approved in 01/2021.