PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

VYNDAQEL®

Soft Capsules 12.2 mg

Each soft capsule contains: tafamidis (as meglumine) 12.2 mg

Inactive and allergenic ingredients: see section 2 under 'Important information about some of this medicine's ingredients' and the section 6 'Further information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is intended to treat a disease called transthyretin amyloidosis. The disease is caused by impaired function of the transthyretin (TTR) protein, which is essential for carrying various substances in the body, such as hormones.
In patients with this disease, the protein breaks up and may form amyloid fibers. This amyloid can build up around nerve cells (known as transthyretin amyloid polyneuropathy ATTR-PN) and in other places in the body. The amyloid causes the symptoms of this disease. Amyloid buildup prevents nerve cells from working normally. Vyndaqel® can prevent breakdown of the protein and formation of amyloid. This medicine is used to treat transthyretin amyloidosis in adult patients with nerve damage (symptomatic polyneuropathy), to delay disease progression.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

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

Consult with your doctor, pharmacist or nurse before starting treatment with this medicine.

Children and adolescents
The symptoms of transthyretin amyloidosis are not manifested in children and adolescents; therefore, the medicine is not intended for use in children and adolescents.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and dietary supplements, inform the doctor or pharmacist.
Particularly if you are taking:

- 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)

Use of the medicine and food
The capsule may be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant, think you are pregnant or are planning to become pregnant, do not use this medicine without consulting your doctor first.
Women of child-bearing age who may become pregnant must use contraceptives during the course of treatment and for one month after stopping treatment.

Driving and use of machines
Vyndaqel® has either no effect or a negligible influence on the ability to drive or use machinery.

Important information about some of this medicine's ingredients
The medicine contains sorbitol
This medicine contains no more than 44 mg sorbitol in each capsule.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use according to the doctor's instructions! Check with your doctor or pharmacist if you are uncertain about the dosage and treatment regimen.
The dosage and the treatment regimen will be determined by the doctor only.
The recommended dosage is one capsule (20 mg) per day, with or without food.
Swallow the capsule whole; do not halve. Do not open and spread the contents of the capsule.

If you vomit shortly after taking the capsule, and can identify the capsule in the vomit, take an additional capsule the same day (as long as the status of your digestive system permits). If you cannot identify the capsule, do not take an additional dose, and continue taking the preparation the next day, as planned.
Complete the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. Discontinuing the treatment may cause disease progression.

Do not exceed the recommended dose.

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the scheduled time, take a dose as soon as you remember. If you remember close to the time for the next dose, skip the forgotten dose and take the next dose as planned. Never take a double dose to compensate for a forgotten dose!
Adhere to the treatment regimen recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very common side effects (may occur in more than 1 in 10 people):
Diarrhea, urinary tract infection (symptoms may include: frequent need to urinate, pain or a burning sensation when urinating), vaginal infection in women, abdominal pain.

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

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 SHOULD THE MEDICINE BE STORED?

- Prevent poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Polyethylene Glycol, Gelatin Clear, Gelatin (195 AH 8), Sorbitol Special Glycerin Bland, Polysorbate 80, Sorbitan Monooleate, Titanium Dioxide, Iron Oxide Yellow, Ink Purple Opacode (WB).

Each soft capsule contains no more than 44 mg of sorbitol.

What the medicine looks like and the contents of the package:
A soft, opaque yellow colored capsule, with "VYN 20" imprinted on it in red.
The package contains two blisters of 15 soft capsules each – a total of 30 soft capsules per package.

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

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 154-10-34016-00.

Revised in 03/2022 according to MOH guidelines.