

Patient leaflet 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 section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, consult your 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 THIS 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 THIS 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 nonprescription medicines and dietary supplements, tell your 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)

Using this medicine and food

The capsule may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant, think you are pregnant, are planning to become pregnant or breastfeeding, 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. Sorbitol is a source of fructose.

3. HOW TO USE THIS MEDICINE?

Always use according to your 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 your 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 your doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting your doctor. Discontinuing the treatment may cause disease progression.

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. 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 as recommended by your 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 any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Vyndaqel, may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience 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), 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 your 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 TO STORE THE MEDICINE?

- 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 a 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, this 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 contents of the pack:

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 Pituach 46725.

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

Revised in 12/2023 according to MOH guidelines.