

VYNDAMAX[®] SOFT CAPSULE

Tafamidis (61 mg)

What is in this leaflet

1. What Vyndamax is used for
2. How Vyndamax works
3. Before you use Vyndamax
4. How to use Vyndamax
5. While you are using it
6. Side Effects
7. Storage and Disposal of Vyndamax
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What Vyndamax is used for

Vyndamax contains the active substance tafamidis, which is a selective stabiliser of transthyretin (TTR). Vyndamax is a prescription medicine used in the treatment of wild type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).

How Vyndamax works

Vyndamax is a medicine which treats a disease called transthyretin amyloidosis. Transthyretin amyloidosis is caused by a protein called transthyretin (TTR) that does not work properly. TTR is a protein that carries other substances, such as hormones, through the body.

In patients with this disease, TTR breaks up and may form fibres called amyloid. Amyloid can build up between cells in your heart (known as transthyretin amyloid cardiomyopathy or ATTR-CM) and in other places in your body. The amyloid causes the symptoms of this disease. When this occurs in your heart, it prevents your heart from working normally.

Vyndamax can prevent TTR from breaking up and forming amyloid. This medicine is used to treat adult patients whose heart has been affected (people with symptomatic cardiomyopathy).

Before you use Vyndamax

- When you must not use it

If you are allergic to tafamidis or any of the other ingredients of this medicine.

Children and adolescents

Children and adolescents do not have the symptoms of transthyretin amyloidosis. Vyndamax is therefore not used for children and adolescents.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Vyndamax if you are pregnant or breast-feeding.

Women of childbearing potential should use birth control during treatment and for one month after stopping treatment.

- Before you start to use it

Talk to your doctor or pharmacist before taking Vyndamax.

Vyndamax contains no more than 44 mg sorbitol in each capsule. Sorbitol is a source of fructose.

Vyndamax should be discontinued in patients who undergo organ transplantation.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should inform your doctor or pharmacist if you are taking any of the following:

- non-steroidal anti-inflammatory drugs
- 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)

How to use Vyndamax

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose is one Vyndamax 61 mg (tafamidis) capsule taken once a day.

- Vyndamax is for oral use.
- The soft capsule should be swallowed whole, not crushed or cut.
- The capsule may be taken with or without food.

If you vomit after taking this medicine and can identify the intact Vyndamax capsule, then an additional dose of Vyndamax should be taken in the same day; if you cannot identify the Vyndamax capsule, then no additional dose of Vyndamax is necessary, and you can resume taking Vyndamax the next day as usual.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Vyndamax for as long as your doctor recommends.

- If you forget to use it

If you forget to take a dose, take your capsules as soon as you remember. If it is almost time for the next dose, skip

VYNDAMAX[®] SOFT CAPSULE

Tafamidis (61 mg)

the missed dose and take the next dose at the usual time. Do not

take a double dose to make up for a forgotten dose.

Consult your doctor or pharmacist on what you should do if you are not sure.

- *If you use too much (overdose)*

You should not take more capsules than your doctor tells you to. If you take more capsules than you have been told to take, contact your doctor immediately or go to the Emergency Department of your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Vyndamax.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Vyndamax to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

Vyndamax is believed to have no or negligible influence on the ability to drive and use machines.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects: may affect up to 1 in 10 people

- Diarrhoea
- Rash, itching

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

In clinical studies, the side effects in patients taking Vyndamax were generally similar to that of patients not taking Vyndamax. Flatulence and increase in liver function tests were reported more often in ATTR-CM patients treated with Vyndamax. Decrease in thyroxine may occur.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [Consumer→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Vyndamax

- *Storage*

Store below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister card and on the carton. The expiry date refers to the last day of that month.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Vyndamax soft capsules are reddish brown, opaque, oblong (approximately 21 mm) printed with “VYN 61” in white.

- *Ingredients*

- *Active ingredient*

The active substance is tafamidis. Each capsule contains 61 mg micronized tafamidis.

- *Inactive ingredients*

Capsule Content

Macrogol 400
Polysorbate 20
Povidone
Butylated Hydroxytoluene

Capsule Shell

Gelatine
Glycerine
Red iron oxide
Sorbitan
Sorbitol
Mannitol
Purified water

Printing Ink (Ink, White Opacode)

Ethyl Alcohol
Ammonium Hydroxide 28%
Isopropyl Alcohol
Purified Water
Macrogol 400
Polyvinyl Acetate Phthalate
Propylene Glycol
Titanium Dioxide

- *MAL number(s):*

Vyndamax soft capsule 61 mg:

MAL22086001ACRZ

Manufacturer

Catalent Pharma Solutions, LLC
2725 Scherer Drive North
St. Petersburg, FL 33716
USA

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11

VYNDAMAX[®] SOFT CAPSULE

Tafamidis (61 mg)

Wisma Averis, Tower 2
Avenue 5, Bangsar South
No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

Date of Revision

14/05/2024

Serial Number

NPRA (R1/2) 04052024/085

PLD-VYNDAMAX-0524