

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VYNDAMAX™

Tafamidis capsules

Read this carefully before you start taking **VYNDAMAX** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VYNDAMAX**.

What is VYNDAMAX used for?

VYNDAMAX is used to treat adults with cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM). Cardiomyopathy is a disease of the heart muscle that makes it harder for your heart to pump blood to the rest of your body. VYNDAMAX reduces death and hospitalization related to heart problems.

VYNDAMAX is not for use in patients less than 18 years of age.

How does VYNDAMAX work?

VYNDAMAX is used to treat a disease called transthyretin amyloid cardiomyopathy (also known as ATTR-CM). In ATTR-CM, a protein called transthyretin (TTR) breaks up and may form fibrils called amyloid. Amyloid can build up between cells in your heart preventing your heart from working normally. This can cause heart-related symptoms and problems. VYNDAMAX is used to prevent the TTR protein from breaking up and slows the deposit of amyloid fibrils in the heart.

What are the ingredients in VYNDAMAX?

Medicinal ingredients: tafamidis

Non-medicinal ingredients: ammonium hydroxide 28%, butylated hydroxytoluene, gelatin, glycerin, iron oxide (red), polyethylene glycol 400, polysorbate 20, povidone (K value 90), polyvinyl acetate phthalate, propylene glycol, sorbitol, and titanium dioxide

VYNDAMAX comes in the following dosage forms:

Capsules: 61 mg

Do not use VYNDAMAX if:

- You are allergic to tafamidis or any of the ingredients in this medicine, including non-medicinal ingredients, or component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take [VYNDAMAX]. Talk about any health conditions or problems you may have, including if you:

- have liver problems
- have severe kidney problems
- had an organ transplant

- are pregnant or plan to become pregnant. VYNDAMAX may harm your unborn baby. Tell your healthcare professional right away if you become pregnant or think you may be pregnant during treatment with VYNDAMAX. If you are a woman of childbearing potential, you should use appropriate contraception during treatment with VYNDAMAX. You should also continue to use appropriate contraception for one month after stopping treatment.
- are breast-feeding or plan to breast-feed. It is not known if VYNDAMAX passes into breast milk. You should not breast-feed during treatment with VYNDAMAX. Talk to your healthcare professional about the best way to feed your baby during treatment with VYNDAMAX.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VYNDAMAX:

- midazolam and triazolam, sedative drugs
- methotrexate and imatinib, drugs used to treat cancer
- rosuvastatin and pravastatin, drugs used to lower cholesterol
- olmesartan, used to treat high blood pressure
- acetylsalicylic acid, ibuprofen, naproxen, and other non-steroidal anti-inflammatory drugs
- drugs used to treat HIV/AIDS
- diuretics or water pills, used to treat high blood pressure

How to take VYNDAMAX:

- Take VYNDAMAX exactly as your healthcare professional tells you to.
- VYNDAMAX capsules should be swallowed whole and not crushed or cut open.

Usual dose:

- Take one (1) VYNDAMAX 61 mg capsule once a day, with or without food.
- Your healthcare professional may reduce your dose to one capsule of 20 mg VYNDAQEL (tafamidis meglumine) if you can't tolerate the usual VYNDAMAX dose (for information on tafamidis meglumine 20 mg, See Product Monograph for VYNDAQEL, **PATIENT MEDICATION INFORMATION**).

Overdose:

If you think you, or a person you are caring for, have taken too much VYNDAMAX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regularly scheduled time. Do not take 2 doses at the same time.

What are possible side effects from using VYNDAMAX?

These are not all the possible side effects you may have when taking VYNDAMAX. If you experience any side effects not listed here, tell your healthcare professional.

- fall
- sinusitis (congested nose)
- asthenia (feeling weak or a lack of energy)
- feeling unbalanced when standing or walking
- cataract (clouding of the lens in your eye)
- Abdominal discomfort (unpleasant sensation in the stomach)
- Abdominal pain (stomachache)
- Constipation
- Diarrhea
- Pruritis: itching or itchy skin
- Rash

VYNDAMAX may cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Cystitis (bladder infection): increased need to urinate, pain in the pelvis or lower back, frequent urination during the night, cloudy urine that may contain blood, burning sensation when passing urine.		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature (15 to 25°C).
- Keep out of reach and sight of children.

If you want more information about VYNDAMAX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

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