

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rVYNDAQEL

Tafamidis meglumine capsules

Read this carefully before you start taking **VYNDAQEL** 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 **VYNDAQEL**.

What is VYNDAQEL used for?

VYNDAQEL is used in adults to treat a heart disease called transthyretin amyloidosis 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 problems.

How does VYNDAQEL work?

VYNDAQEL works to prevent the TTR protein from breaking up and forming amyloid in the heart. This helps to reduce death and hospitalization related to heart symptoms and problems from ATTR-CM.

What are the ingredients in VYNDAQEL?

Medicinal ingredient: tafamidis meglumine.

Non-medicinal ingredients: ammonium hydroxide 28%, brilliant blue FCF, carmine, gelatin, glycerin, iron oxide (yellow), polyethylene glycol 400, polysorbate 80, polyvinyl acetate phthalate, propylene glycol, sorbitan monooleate, sorbitol, and titanium dioxide.

VYNDAQEL comes in the following dosage forms:

Capsules: 20 mg of tafamidis meglumine.

Do not use VYNDAQEL if:

- you are allergic to tafamidis meglumine or to any of other ingredients in VYNDAQEL.

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

- have severe liver problems.
- have severe kidney problems.
- had an organ transplant.
- are pregnant or plan to become pregnant. VYNDAQEL may harm your unborn baby. Tell your healthcare professional right away if you become pregnant or think you may be pregnant during treatment with VYNDAQEL. If you are a woman of childbearing potential, you should use appropriate birth control during treatment with VYNDAQEL and for one month after stopping treatment.

- are breastfeeding or plan to breastfeed. It is not known if VYNDAQEL passes into breast milk. You should not breastfeed during treatment with VYNDAQEL. Talk to your healthcare professional about the best way to feed your baby during treatment with VYNDAQEL.

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 VYNDAQEL:

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

How to take VYNDAQEL:

Take VYNDAQEL exactly as your healthcare professional tells you to.

VYNDAQEL capsule(s) should be swallowed whole. Do not crush or cut the capsule. VYNDAQEL may be taken with or without food.

Usual dose:

Take four (4) 20 mg capsules of VYNDAQEL once a day (for a total of 80 mg).

If you can't tolerate the usual dose of VYNDAQEL once a day, your dose may be reduced by your healthcare professional.

Note: VYNDAQEL capsules (tafamidis meglumine) and VYNDAMAX capsules (tafamidis) are different formulations. VYNDAQEL and VYNDAMAX capsules are not interchangeable on a per milligram basis. For additional information, see the Product Monograph for VYNDAMAX, **PATIENT MEDICATION INFORMATION**.

Overdose:

If you think you, or a person you are caring for, have taken too much VYNDAQEL, 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 VYNDAQEL?

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

- cataracts (clouding of the lens in your eye);
- cough;
- falls;
- feeling unbalanced when standing or walking;
- feeling weak or a lack of energy;
- insomnia (difficulty sleeping);
- muscle spasms;
- swelling or pain in arms, hands, ankles, legs and feet;
- diarrhea;
- rash;
- pruritis (itching or itchy skin).

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			
Hematuria (blood in the urine): pink, red, or very dark urine.		x	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, or fatigue (may occur when you go from lying or sitting to standing up).		x	
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, or 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.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 healthcare 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°C to 25°C).
- Keep out of reach and sight of children.

If you want more information about VYNDAQEL:

- 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.

This leaflet was prepared by Pfizer Canada ULC.

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