

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

VYNDAQEL
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 a prescription medicine used to treat adults with cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) to reduce death and hospitalization related to heart problems.

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

How does VYNDAQEL work?

VYNDAQEL is used to treat a 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 symptoms and problems. VYNDAQEL 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 VYNDAQEL?

Medicinal ingredients: 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 form:

Capsules: 20 mg

Do not use VYNDAQEL if:

- You are allergic to tafamidis meglumine or any of the ingredients in this medicine

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 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 contraception 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 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 VYNDAQEL:

Take VYNDAQEL exactly as your healthcare professional tells you to. VYNDAQEL capsule(s) should be swallowed whole and not crushed or cut.

Usual dose:

Take four (4) VYNDAQEL 20 mg capsules (for a total of 80 mg of VYNDAQEL) once a day, with or without food.

Your dose may be reduced to 20 mg once a day if you can't tolerate the usual dose.

Overdose:

If you think you have taken too much VYNDAQEL, contact your 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 feel when taking VYNDAQEL. If you experience any side effects not listed here, contact your healthcare professional.

- fall
- congested nose
- feeling weak or a lack of energy
- feeling unbalanced when standing or walking
- cataract (clouding of the lens in your eye)

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 becomes bad enough to interfere with your daily activities, talk to 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 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); 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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