

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VYNDAMAX®

tafamidis

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Vyndamax. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Vyndamax against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Vyndamax is used for

Your medicine, which contains tafamidis, is used to treat a disease called transthyretin amyloid cardiomyopathy, also known as ATTR-CM.

In patients with ATTR-CM, a protein called transthyretin (TTR) breaks up and may form fibrils called amyloid. Amyloid can build up between cells in your heart and in other places in your body, preventing your heart from working normally and causing symptoms.

Vyndamax is used to prevent TTR from breaking up and forming amyloid.

This medicine belongs to a group of medicines called transthyretin stabilisers.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

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

This medicine is not recommended for use in children as ATTR-CM is not a condition common in children.

Before you take Vyndamax

When you must not take it

Do not take Vyndamax if you have an allergy to:

- any medicine containing tafamidis
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in Vyndamax may pass into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- an illness requiring an organ transplant
- a medical condition affected by excessive sorbitol
- severe liver problems

- severe kidney problems.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you are able to become pregnant, you must use birth control while you are taking Vyndamax and should continue using birth control for one month after stopping treatment with Vyndamax.

There are no data on the use of Vyndamax in pregnant women.

If you have not told your doctor about any of the above, tell him/her before you start taking Vyndamax.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Vyndamax may interfere with each other. These include:

- methotrexate, a medicine used to treat rheumatoid arthritis or some cancers
- rosuvastatin, a medicine used to treat high cholesterol
- imatinib, a medicine used for some cancer treatment.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Vyndamax

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Take one 61 mg capsule once a day.

One 61 mg Vyndamax capsule will produce the same level of active ingredient in your blood and give the same effect as four 20 mg capsules of Vyndaquel (total dose = 80 mg), even though one milligram of Vyndamax is not the same as one milligram of Vyndaquel.

Do not take Vyndamax and Vyndaquel at the same time.

How to take it

Swallow the capsule whole with a full glass of water.

The capsule should not be crushed or cut.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is within 6 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Vyndamax. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Vyndamax

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Vyndamax.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Vyndamax to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Vyndamax affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Vyndamax.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling weak or a lack of energy
- feeling unbalanced when standing or walking
- fall
- sinusitis
- cataract (clouding of the lens in your eye)
- flatulence
- muscle or joint pain
- skin ulcer
- bladder infection
- excessive sweating.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using Vyndamax

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store Vyndamax or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Vyndamax 61 mg is a reddish brown, opaque, oblong capsule printed with "VYN 61" in white.

They are supplied in blister packs of 30 capsules.

Ingredients

Vyndamax contains 61 mg of tafamidis as the active ingredient.

- Butylated hydroxytoluene
- Ethanol

- Gelatin
- Glycerol
- Iron oxide red
- Isopropyl alcohol
- Polysorbate 20
- Polyvinyl acetate phthalate
- Povidone
- Propylene glycol
- Macrogol 400
- Mannitol
- Sorbitol
- Strong ammonium solution
- Titanium dioxide.

This medicine does contain sulfites.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Vyndamax is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney, NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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