

Vyndamax[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Vyndamax?

Vyndamax contains the active ingredient tafamidis. Vyndamax is used to treat a disease called transthyretin amyloid cardiomyopathy, also known as ATTR-CM.

For more information, see Section [1. Why am I using Vyndamax?](#) in the full CMI.

2. What should I know before I use Vyndamax?

Do not use if you have ever had an allergic reaction to Vyndamax or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Vyndamax?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Vyndamax and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Vyndamax?

- Take one 61 mg capsule once a day.

More instructions can be found in Section [4. How do I use Vyndamax?](#) in the full CMI.

5. What should I know while using Vyndamax?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using Vyndamax.• If you become pregnant while taking this medicine, tell your doctor immediately.
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Things you should not do	<ul style="list-style-type: none"> Do not stop using this medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> Be careful driving or operating machinery until you know Vyndamax affects you.
Looking after your medicine	<ul style="list-style-type: none"> Keep your capsules in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Vyndamax?](#) in the full CMI.

6. Are there any side effects?

Common side effects include diarrhoea, 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 infections and excessive sweating.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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[®] (vin-der-max)

Active ingredient(s): tafamidis (ter-fam-e-dis)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vyndamax. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Vyndamax.**

Where to find information in this leaflet:

- [1. Why am I using Vyndamax?](#)
- [2. What should I know before I use Vyndamax?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Vyndamax?](#)
- [5. What should I know while using Vyndamax?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Vyndamax?

Vyndamax contains the active ingredient tafamidis.

Vyndamax 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.

2. What should I know before I use Vyndamax?

Do not use Vyndamax if:

1. You are allergic to tafamidis, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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 and/or rash, itching or hives on the skin.

2. You are pregnant.
3. You are breast feeding.
4. You are aged under 18 years.

Check with your doctor if you:

- Have any other medical conditions including:
 - An illness requiring an organ transplant
 - A medical condition affected by excessive sorbitol
 - Severe liver problems
 - Severe kidney problems.
- Have allergies to any other medicines, foods, preservatives or dyes
- Take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with Vyndamax and affect how it works. 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Vyndamax.

4. How do I use Vyndamax?

How much to take

- Take one 61 mg capsule once a day.
- Follow the instructions provided and use Vyndamax until your doctor tells you to stop.

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 Vyndaqel (total dose = 80 mg), even though one milligram of Vyndamax is not the same as one milligram of Vyndaqel.

Do not take Vyndamax and Vyndaqel at the same time.

When to take Vyndamax

- Take your medicine at about the same time each day.
- It does not matter if you take this medicine with or without food.

How to take Vyndamax

- Swallow the capsule whole with a full glass of water.
- The capsule should not be crushed or cut.

If you forget to take Vyndamax

Vyndamax should be used regularly at the same time each day. If you miss your dose at the usual time, and 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 you missed.

If you take too much Vyndamax

If you think that you have taken too much Vyndamax, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Vyndamax?

Things you should 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.

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.

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

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Vyndamax affects you.

Looking after your medicine

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

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• diarrhoea• 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	Speak to your doctor if you have any of these side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Vyndamax contains

Active ingredient (main ingredient)	61 mg tafamidis
Other ingredients (inactive ingredients)	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
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Do not take this medicine if you are allergic to any of these ingredients.

This medicine contains sulfites.

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

What Vyndamax 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.

AUST R 314813

Who distributes Vyndamax

Pfizer Australia Pty Ltd

Sydney, NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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