AMVUTTRA®

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 Amvuttra?

Amvuttra contains the active ingredient vutrisiran. Amvuttra is used to treat an illness called transthyretin-mediated amyloidosis (ATTR amyloidosis).

For more information, see Section 1. Why am I using Amvuttra? in the full CMI.

2. What should I know before I use Amvuttra?

Do not use if you have ever had an allergic reaction to Amvuttra 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 Amvuttra? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Amvuttra 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 Amvuttra?

- Amvuttra may be given by your doctor, nurse, a caregiver or yourself as an injection under the skin.

More instructions can be found in Section 4. How do I use Amvuttra? in the full CMI.

5. What should I know while using Amvuttra?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are using Amvuttra. • Tell your doctor if you are pregnant or breastfeeding, or planning to become pregnant.
Things you should not do	• Your doctor will tell you when you need to receive Amvuttra. Do not stop treatment with Amvuttra unless your doctor tells you to. • Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
Driving or using machines	• Amvuttra has no or negligible influence on the ability to drive or use machines.
Looking after your medicine	• Keep this medicine where young children cannot reach it. • Do not use this medicine after the expiry date which is stated on the label, tray lid and carton after EXP. The expiry date refers to the last day of that month. • Store below 30°C. Do not freeze.

For more information, see Section 5. What should I know while using Amvuttra? in the full CMI.

6. Are there any side effects?

Common side effects may include redness, pain, itching, bruising, or warmth at the injection site. Blood tests may show increases in liver enzymes called alkaline phosphatase and alanine transaminase.

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.

AMVUTTRA®

Active ingredient(s): *vutrisiran*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Amvuttra. **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 Amvuttra.**

Where to find information in this leaflet:

1. Why am I using Amvuttra?

Amvuttra contains the active ingredient vutrisiran.

Amvuttra is used to treat an illness called transthyretin-amyloidosis (ATTR amyloidosis). This illness can run in families and may also be caused by aging.

- ATTR amyloidosis is caused by problems with a protein in the body called 'transthyretin' (TTR).
- This protein is made mostly in the liver and carries vitamin A and other substances around the body.
- In people with this illness, small fibres of TTR protein clump together to make deposits called 'amyloid'.
- Amyloid can build up around or within the nerves, heart, and other places in the body, stopping them from working normally. This causes the symptoms of the illness.

Amvuttra works by lowering the amount of TTR protein made by the liver which means there is less TTR protein in the blood that can form amyloid. This can help to reduce the effects of this illness. Amvuttra is used in adults only.

2. What should I know before I use Amvuttra?

Warnings

Do not use Amvuttra if:

- you are allergic to vutrisiran, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- 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?

Lowered vitamin A levels

Amvuttra lowers the amount of vitamin A in your blood. Your doctor will ask you to take a daily vitamin A supplement. Please follow the vitamin A dose recommended by your doctor.

Signs of low vitamin A may include: sight problems especially at night, dry eyes, hazy, or cloudy vision.

Both too high and too low levels of vitamin A can harm the development of your unborn child. Therefore, women of childbearing age should exclude any pregnancy before starting treatment with Amvuttra and practice effective contraception (see section "Pregnancy and breastfeeding" below).

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Amvuttra can impact the level of Vitamin A in your blood, this might increase the risk of fetal defects.

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

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.

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

4. How do I use Amvuttra?

How to use Amvuttra

Amvuttra may be self-administered or administered by a caregiver, doctor or nurse.

Your doctor or nurse will show you or your caregiver how to inject Amvuttra before you do it yourself.

For instructions on how to use Amvuttra, refer to the Instructions for Use section of this CMI.

How much to use

- One injection, with the recommended dose 25 mg is given under your skin every 3 months.
- The injection will be given in your stomach area (abdomen), upper arm (if given by someone else) or thigh.

When to use Amvuttra

- Amvuttra injection should be given every 3 months.

If you forget to use Amvuttra

Amvuttra should be given regularly. If you miss your dose at the usual time, take the next dose of Amvuttra as soon as possible. The next dose should follow 3 months later.

If you use too much Amvuttra

Amvuttra is a pre-filled syringe for single use only. In the unlikely event that you take too much Amvuttra (an overdose), 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.

Instructions for Use

Important Warnings

Do not use if the carton is damaged or shows signs of tampering.

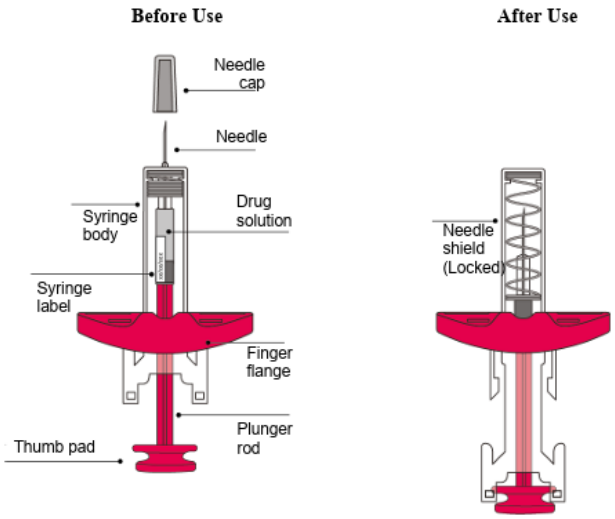
Do not use the syringe if it was dropped on a hard surface.

Do not touch the plunger rod until ready to inject.

Do not remove the needle cap until just before injection.

Do not recap the syringe at any time.

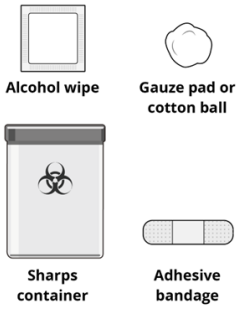
How the syringe looks



1. Gather Supplies

Gather and place the following supplies (not supplied) on a clean flat surface:

- Alcohol wipe
- Gauze pad or cotton ball
- Adhesive bandage
- Sharps container

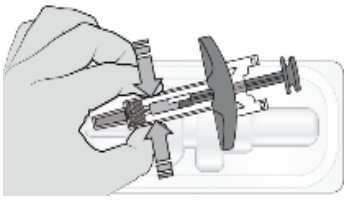


2. Prepare the syringe

If stored cold, allow the syringe to warm to room temperature for 30 minutes before using.

- **Do not** warm the syringe in any other way, e.g., microwave, hot water, or near other heat sources.

Remove the syringe from the packaging by gripping the syringe body.

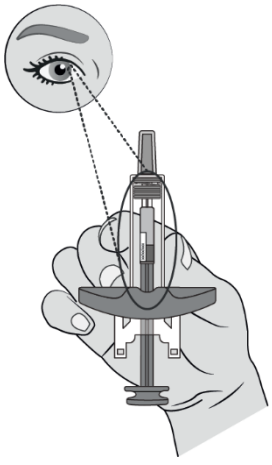


- **Do not** touch plunger rod until ready to inject.
- **Do not** use the syringe if it was dropped on a hard surface.
- **Do not** remove the needle cap until just before injection.

3. Check the syringe

Check:

- Syringe is not damaged, such as cracked or leaking
- Needle cap is intact and attached to the syringe
- The drug solution in the syringe is clear, and colourless-to-yellow.
- "Amvuttra 25 mg" appears on the syringe label.
- Expiry date on syringe label.



It is normal to see air bubbles inside the syringe.

Do not use the syringe if any issues are found while checking the syringe and drug solution

Do not use if the expiry date has passed.

Do not use if the drug solution contains particulate matter or if it is cloudy or discoloured.

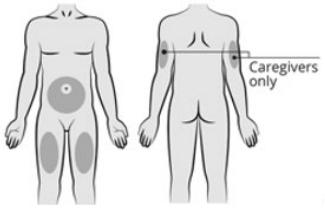
Contact healthcare provider if any issues are found.

4. Choose injection site

Choose an injection site from the following areas:

- Abdomen, except for the 5 cm (2 inches) area around the belly button (navel).
- Front of the thighs.
- If someone else is giving the injection, then the back of the upper arms can be used as well.

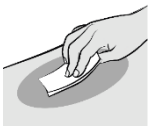
Do not inject into areas of skin that are tender, red, swollen, bruised or hard or within 5 cm (2 inches) of the belly button (navel).



5. Prepare for injection

Wash hands with soap and water and dry thoroughly with a clean towel.

Clean the chosen injection site using an alcohol wipe. Allow the skin to air-dry before injecting. Avoid touching or blowing on the injection site after cleaning.



6. Remove the needle cap

Hold the syringe body with one hand. Pull the needle cap straight off with other hand and dispose of needle cap immediately. It is normal to see a drop of liquid at the tip of the needle.

Do not touch the needle or let it touch any surface.

Do not recap the syringe.

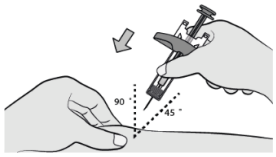
Do not pull on the plunger rod.

Do not use the syringe if it was dropped on a hard surface.

7. Insert Needle

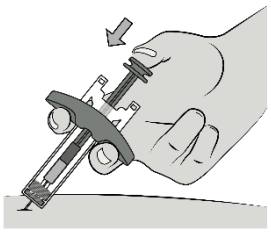
Using the free hand, gently pinch the cleaned skin around the injection site to create a bump for the injection.

Fully insert the needle into the pinched skin at a 45-90° angle.

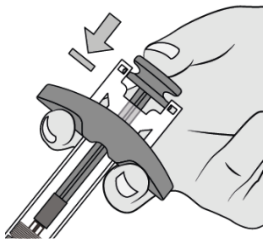


8. Inject Medicine

Using the thumb pad, push the plunger rod while grasping the finger flange.



Push the plunger rod all the way down, as far as it will go, to inject all of the drug solution.



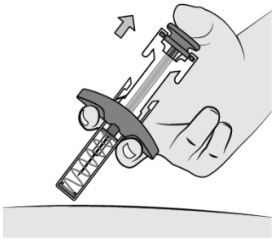
The plunger rod must be pressed **all the way down** to administer the dose.

9. Release Plunger Rod

Release the plunger rod to cover the needle.

Remove the syringe from the skin.

Do not block plunger rod movement.



Do not pull down on the needle shield. The needle shield automatically covers the needle.

10. Check Injection Site

There may be a small amount of blood or liquid at the injection site.

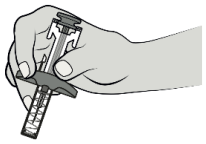
If so, apply pressure over the injection site with a gauze pad or cotton ball until any bleeding stops.

Avoid rubbing the injection site.

11. Dispose of Syringe

Immediately dispose of the used syringe into a sharps container.

Only use a sharps container to dispose of syringes.



5. What should I know while using Amvuttra?

Things you should do

If you notice a change in your vision or any other eye problems whilst using Amvuttra, talk to your doctor. Your doctor may send you to an eye specialist for a check-up.

If you are a woman of childbearing age, you should practice effective contraception during treatment with Amvuttra.

Tell your doctor if you are planning to become pregnant. Your doctor may tell you to stop taking Amvuttra. Your doctor will ensure your vitamin A levels have returned to normal before you try to become pregnant. Vitamin A levels may remain low for more than 12 months after the last dose of Amvuttra.

Remind any doctor, dentist or pharmacist you visit that you are given Amvuttra.

Things you should not do

Your doctor will tell you how long you need to receive Amvuttra. Do not stop treatment with Amvuttra unless your doctor tells you to.
Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

Driving or using machines

Amvuttra is unlikely to affect your ability to drive or use machines. Your doctor will tell you whether your condition allows you to drive vehicles and use machines safely.

Looking after your medicine

- Do not use this medicine after the expiry date, which is stated on the label, tray lid and carton after EXP. The expiry date refers to the last day of that month.
- This medicine is for single use only. Once the product is opened, use immediately.
- Store below 30 °C. Do not freeze.

Keep the medicine where young children cannot reach it.

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.

Do not use this medicine after the expiry date.

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.

Less serious side effects

Less serious side effects	What to do
Local reactions: • redness, pain, itching, bruising, or warmth where the injection was given Blood tests: • increased liver enzymes (alkaline phosphatase, alanine transaminase)	Speak to your doctor if you have any of these less serious 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 Amvuttra contains

Active ingredient (main ingredient)	Vutrisiran
Other ingredients (inactive ingredients)	Monobasic sodium phosphate dihydrate Dibasic sodium phosphate dihydrate Sodium chloride Water for injections Sodium hydroxide Phosphoric acid

Do not take this medicine if you are allergic to any of these ingredients.

The syringe components are not made with natural rubber latex.

What Amvuttra looks like

Amvuttra is a clear, colourless to yellow solution.

Amvuttra is provided in a single-use pre-filled syringe with a needle and needle shield.

Each syringe of Amvuttra contains 0.5 mL of solution for injection.

AUST R 422290.

Who sponsors Amvuttra®

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This leaflet was prepared in April 2026.

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