ADZYNMA®

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 ADZYNMA?

ADZYNMA contains the active ingredient apadamtase alfa/cinaxadamtase alfa, which is a recombinant form of the human protein enzyme ADAMTS13 (rADAMTS13). ADZYNMA is used as an enzyme replacement to replenish the ADAMTS13 level in patients with congenital thrombotic thrombocytopenic purpura (cTTP). ADZYNMA can be used for all age groups. For more information, see Section 1. Why am I using ADZYNMA? in the full CMI.

2. What should I know before I use ADZYNMA?

Do not use if you have ever had sudden, severe or potentially life-threatening allergic reaction to ADZYNMA, or to any of the other ingredients listed at the end of the CMI. Talk to your doctor if you take any other medicines, or if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed. For more information, see Section 2. What should I know before I use ADZYNMA? in the full CMI.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines including any that you get without a prescription from your pharmacy, supermarket, or health food shop. For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given ADZYNMA?

- ADZYNMA will be prepared and given to you by a qualified healthcare professional who is experienced in the care of patients with blood disorders. Some individuals (and/or their caregivers) may be trained to use ADZYNMA at home.
- Your doctor will decide on your dose of ADZYNMA depending on your body weight.

- The frequency of infusions you receive will depend on how well ADZYNMA works for you, and whether you are using ADZYNMA for sudden episodes of your condition.
- ADZYNMA is slowly injected directly into your veins. Before injection, the ADZYNMA powder must be mixed and dissolved using the solvent supplied.

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

5. What should I know while using ADZYNMA?

Things you should do	• Tell your doctor immediately if - you notice any sudden signs and symptoms of a severe allergic reaction. - you think ADZYNMA is not working for you. • Keep a record of the name and batch number of the medicine you received.
Things you should not do	• Do not stop using your medicine or change the dosage without checking with your doctor.

Driving or using machines	• Be careful before you drive or use any machines until you know how ADZYNMA affects you.
Looking after your medicine	• Keep ADZYNMA in the pack until it is time to use it so that it is protected from light. • Keep ADZYNMA in the refrigerator at 2°C to 8°C. Do not freeze.

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

6. Are there any side effects?

Very common side effects include nose and throat infection, headache, feeling dizzy, migraine, diarrhoea, nausea. Common side effects include high number of platelets in the blood, feeling sleepy, constipation, bloating, weakness, feeling hot, ADAMTS13 activity abnormal. 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 http://www.tga.gov.au/reporting-problems.

ADZYNMA®

Active ingredient(s): *apadamtase alfa/cinaxadamtase alfa [rADAMTS13]*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ADZYNMA.

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 ADZYNMA.

Where to find information in this leaflet:

1. Why am I using ADZYNMA?

ADZYNMA contains the active ingredients apadamtase alfa/cinaxadamtase alfa (rADAMTS13).

ADZYNMA is used as an enzyme replacement therapy in patients with congenital thrombotic thrombocytopenic purpura (cTTP) who are lacking the ADAMTS13 enzyme.

Thrombotic thrombocytopenic purpura (TTP) is a very rare blood disorder in which blood clots form in small blood vessels throughout the body. These clots can block the flow of blood and oxygen to the body's organ which leads to a lower-than-normal number of platelets in the blood.

Patients with cTTP are born with this condition due to a lack of the ADAMTS13 enzyme in the blood. ADAMTS13 helps prevent blood clots by breaking down large molecules called von Willebrand factor (VWF). When VWF molecules are too large, they can cause dangerous blood clots.

ADZYNMA is a form of ADAMTS13, that is produced in a laboratory by recombinant DNA technology.

ADZYNMA works as a replacement therapy to replenish the levels of the lacking ADAMTS13 enzyme. This helps break up the large molecules of VWF into smaller ones, reducing the likelihood of blood clots forming and potentially preventing low blood platelet levels in patients with cTTP.

This medicine helps to control your condition but does not cure it.

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 ADZYNMA?

Warnings

Do not use ADZYNMA if you have ever had sudden, severe or potentially life-threatening allergic reaction to:

- the active ingredient of ADZYNMA
- any of the other ingredients listed at the end of this leaflet.

Signs and symptoms of an allergic reaction may include:

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

Always check the ingredients to make sure you can use this medicine. If you are unsure about this, ask your doctor.

Pregnancy and breastfeeding

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

Your doctor will discuss the risks and benefits of using ADZYNMA if you are pregnant. Only use ADZYNMA during pregnancy if your doctor specifically recommends it.

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

It is not known if ADZYNMA passes into your milk and if it can harm your baby. Your doctor will discuss the risks and benefits of using ADZYNMA if you are breastfeeding.

3. What if I am taking other medicines?

Talk to your doctor or healthcare professional 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.

Your doctor will have more information on medicines to be careful with or avoid if you have concerns.

4. How do I use ADZYNMA?

Treatment with ADZYNMA will be given to you under the supervision of your doctor or qualified healthcare professional who is experienced in the care of patients with blood disorders.

After starting ADZYNMA treatment, you and/or your caregiver may be trained by a healthcare professional to self-inject ADZYNMA at home.

How much to use

Follow all directions given to you by your doctor carefully.

Your doctor will decide on your dose of ADZYNMA depending on your body weight.

Your doctor will tell you how often or at what intervals you will receive the injection.

The frequency of injections you receive will depend on how ADZYNMA works for you.

For preventative enzyme replacement therapy, the usual dose is:

- 40 IU per kg of body weight, given every other week.
- Your doctor may change the frequency to once weekly if ADZYNMA every other week is not working for you.

For on-demand replacement therapy if you develop a sudden episode of TTP, the recommended dose is:

- 40 IU per kg of body weight on day 1,

- 20 IU per kg of body weight on day 2,
- 15 IU per kg of body weight starting on day 3 once daily until 2 days after the sudden episode of TTP is resolved.

How to use ADZYNMA

- ADZYNMA is slowly injected directly into your vein.

Do not attempt to inject ADZYNMA by yourself unless you have received proper training by your doctor or healthcare professionals on how to use the product.

Preparing ADZYNMA

- ADZYNMA is provided as a powder in a vial, co-packaged with a solvent vial containing water for injections. Before use, the ADZYNMA powder must be mixed and dissolved using the provided solvent to form a clear solution.
- Follow carefully the step-by-step instructions at the end of this leaflet or in the pack insert on how to prepare and inject ADZYNMA.
- Do not mix ADZYNMA with any other medicines or solvent other than the water for injections solvent supplied with the pack.
- Use only the reconstitution device provided with each pack to prepare the solution for injection.
- After mixing the powder and the solvent, use the solution immediately. If the solution is not used straight way, you can keep the solution for a maximum of 3 hours when stored at room temperature (below 30°C).

- Do not refrigerate the solution after it is prepared.
- ADZYNMA is for single use in one patient only.
- Dispose of all unused solution, empty vials, and used needles and syringes into a sharps bin.

The step-by-step instructions can be found under Instructions for use.

If you are unsure about how to prepare the medicine for use, contact your doctor or healthcare professional.

Inspecting ADZYNMA

- Always inspect ADZYNMA before use and after it has been mixed.
- After mixing, the solution should be clear to colourless, and free from foreign particles.
- Do not inject the solution if it is discoloured, or cloudy, or contains particles.

Instructions for use:

This instructions for use are intended only for healthcare professionals and for those patients or caregivers who have been trained by their doctor or healthcare professional on the proper way to self-inject the medicine.

Contact your doctor or healthcare professional if you have any questions or if you experience any problems following this instruction guide.

IMPORTANT

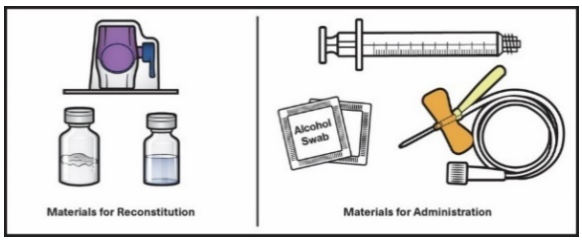
- **Before injecting ADZYNMA into the vein, the ADZYNMA powder must be mixed and dissolved using the provided solvent to form a clear solution.**
- Use aseptic technique throughout the procedure.
- Before use, check the expiry date of the product which is printed on the label after the word 'EXP'. The expiry date refers to the last day of the month.
- **Do not use ADZYNMA if the expiry date has passed.**
- If more than one vial of ADZYNMA is needed for the dose, mix each vial of ADZYNMA using a separate BAXJECT II Hi-Flow supplied in each pack.
- Always inspect ADZYNMA after it is mixed and before use. The solution should be clear to colourless.
- **Do not use the solution if it is discoloured, or cloudy, or contains particles.**
- After preparing ADZYNMA, use the solution as soon as possible, within 3 hours after mixing.

Do not use ADZYNMA in the same tubing or container at the same time with other medicines.

Reconstitution using the BAXJECT II Hi-Flow device

1. Prepare a clean flat surface and gather all the materials you will need for the reconstitution and administration (Figure A).

Figure A

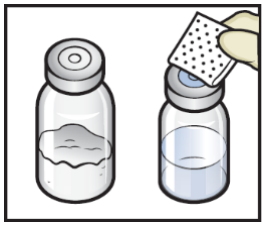


2. Allow the vials of ADZYNMA and solvent vials to reach room temperature before use.
3. Wash and dry your hands thoroughly.
4. Remove plastic caps from the ADZYNMA and diluent vials and place the vials on a flat surface (Figure B).

Figure B

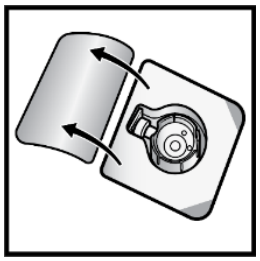
5. Wipe the rubber stoppers with an alcohol swab and allow them to dry prior to use (Figure C).

Figure C



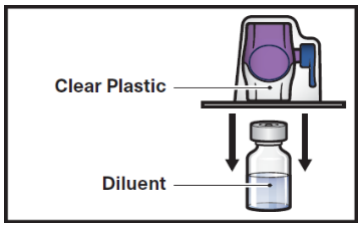
6. Open the BAXJECT II Hi-Flow device package by peeling away the lid, without touching the inside (Figure D).
   - Do not remove the device from the package.
   - Do not touch the clear plastic spike.

Figure D



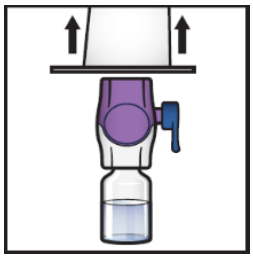
7. Turn the package with the BAXJECT II Hi-Flow device upside down and place it over the top of the diluent vial. Press straight down until the clear plastic spike pierces through the diluent vial stopper (Figure E).

Figure E



8. Grip the BAXJECT II Hi-Flow package at its edge and pull the package off the device (Figure F).
   - Do not remove the blue cap from the device.
   - Do not touch the exposed purple plastic spike.

Figure F



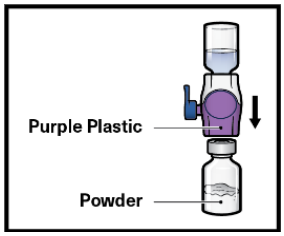
9. Turn the system over so that the solvent vial is on top. Press the BAXJECT II Hi-Flow device straight

down until the purple plastic spike pierces through the ADZYNMA powder vial stopper (Figure G).

The vacuum will draw the solvent into the ADZYNMA powder vial.

- you may notice some bubbles or foam, this is normal and should soon disappear.

Figure G



10. Swirl the connected vials gently and continuously until the powder is completely dissolved (Figure H).
    - Do not shake the vial.

Figure H

11. Visually inspect the reconstituted solution for particulate matter before administration.
    - Do not use the product if particulate matter or discoloration is observed.
12. If the dose requires more than one vial of ADZYNMA, reconstitute each vial using the above steps.

    - Use a different BAXJECT II Hi-Flow device to reconstitute each vial of ADZYNMA and solvent.

Administration of ADZYNMA

13. Take off the blue cap from the BAXJECT II Hi-Flow device (Figure I). Attach a Luer-lock syringe (Figure J).

    - Do not inject air into the system.

Figure I

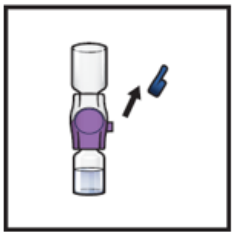
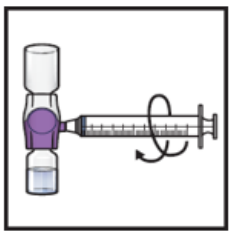
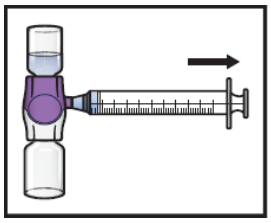


Figure J



14. Turn the system upside down (ADZYNMA vial now on top). Draw the reconstituted solution into the syringe by pulling the plunger back slowly (Figure K).

Figure K

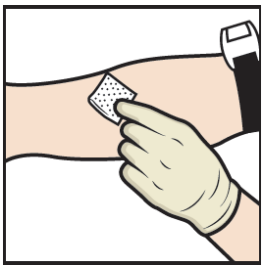


15. If a patient is to receive more than one vial of ADZYNMA, the contents of multiple vials can be drawn into the same syringe. Repeat this process for all reconstituted vials of ADZYNMA until the total volume to be administered is reached.
16. Disconnect the syringe and attach a suitable injection needle or an infusion set.
17. Point the needle up and remove any air bubbles by gently tapping the syringe with your finger and

slowly and carefully pushing air out of the syringe and needle.

18. Apply a tourniquet and clean the chosen injection site with an alcohol swab (Figure L).

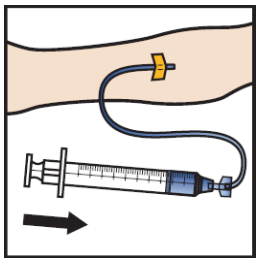
Figure L



19. Insert the needle into the vein and remove the tourniquet.

20. Infuse the reconstituted ADZYNMA slowly, at a rate of 2 to 4mL per minute (Figure M).
    - A syringe pump may be used to control the rate of administration.

Figure M



21. Take the needle out of the vein and put pressure on the injection site for several minutes.
    - Do not recap the needle.

22. Place the needle, syringe, and empty vials in a puncture-resistant sharps container.

Do not dispose of syringes and needles in the household waste.

How long to use ADZYNMA

Continue using ADZYNMA until your doctor tells you to stop.

This medicine helps you to control your condition but does not cure it. Usually, enzyme replacement therapy with ADZYNMA is a life-long treatment. The symptoms of your condition may worsen if you stop treatment.

If you forget to use ADZYNMA

Ask your doctor for advice as soon as possible and continue your next injection as directed.

Do not inject a double dose to make up for the forgotten dose.

If you inject a double dose, this may increase the chance of you getting an unwanted side effect.

If you use too much ADZYNMA

If you think that you have used too much ADZYNMA, you may need urgent medical attention. Taking too much of this medicine may result in bleeding.

You should immediately:

- contact your doctor or healthcare professional, or
- go to the Emergency Department at your nearest hospital, or

- phone the Poisons Information Centre by calling **13 11 26**.

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

5. What should I know while using ADZYNMA?

Things you should do

- Tell you other doctors, dentists and pharmacists you are using this medicine.
- Keep all your doctor's appointments so that your progress can be checked. Your doctor will continue to monitor your response to the treatment.
- For traceability, the name and the batch number of the product should be clearly recorded before use.

Tell your doctor and/or healthcare professional straight away if you notice any sudden signs and/or symptoms of severe allergic reactions.

There is a risk that you may experience an allergic-type hypersensitivity reaction to ADZYNMA. Early signs and symptoms of severe allergic reaction may include:

- fast heart rate
- tightness of the chest
- wheezing and/or sudden onset of difficulty in breathing
- low blood pressure
- hives, rash and itchy skin
- runny nose or nasal congestion

- red eyes
- sneezing
- rapid swelling under the skin in areas such as the face, throat, arms and legs
- tiredness
- nausea (feeling sick)
- vomiting
- sensations like numbness, tingling, pins and needles
- restlessness
- anaphylaxis (severe allergic reaction that can cause difficulty in swallowing and/or breathing, red or swollen face and/or hands).

If any of these symptoms occur, your doctor will decide if your treatment with ADZYNMA should be stopped and will give you appropriate medicines to treat the allergic reaction. Severe symptoms, including difficulty in breathing and dizziness, require prompt emergency treatment.

Tell your doctor if you think ADZYNMA is not working for you.

Neutralising antibodies (called inhibitors) may develop in some patients receiving ADZYNMA. These inhibitors could potentially cause the treatment to stop working properly.

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?

Things you should not do:

- Do not give your medicine to anyone else, even if they appear to have the same condition as you.
- Do not use ADZYNMA to treat any other complaints unless your doctor tells you to.
- Do not stop using ADZYNMA unless advised by your doctor or healthcare professional or unless you have an allergic reaction.
- Do not change 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 ADZYNMA affects you.

The effects of ADZYNMA on the ability to drive or operate machineries have not been performed.

Looking after your medicine

- Keep ADZYNMA in the pack until it is time to use it. This will protect the medicine from light.
- **Keep unopened ADZYNMA in the refrigerator where the temperature is between 2°C to 8°C. Do not freeze.**
- Use ADZYNMA within 3 hours after reconstitution when stored at room temperature.
- Discard any unused reconstituted product after 3 hours.

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

Keep ADZYNMA out of reach of children.

Getting rid of any unwanted medicine

Medicines should not be disposed of via wastewater or household waste.

If your doctor tells you to stop using this medicine, or if the medicine is out of date, or if the medicine has not been stored properly, ask your doctor or healthcare professional what to do with any unwanted medicine that you may have.

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**
Very common: • nose and throat infection • headache	**Speak to your doctor or healthcare professional if you have any of these**

Less serious side effects	What to do
• feeling dizzy • migraine • diarrhoea • nausea Common: • high number of platelets in the blood • feeling sleepy • constipation • bloating • weakness • feeling hot • abnormal ADAMTS13 activity	**less serious side effects and they worry you.**

Tell your doctor, healthcare professional, 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, healthcare professional, or pharmacist before you decide to stop using any of your medicines.

7. Product details

What ADZYNMA contains

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

Powder in a vial

Active ingredient (main ingredient)	apadamtase alfa/ cinaxadamtase alfa (rADAMTS13)
Other ingredients (inactive ingredients)	sodium chloride calcium chloride dihydrate histidine mannitol sucrose polysorbate 80

Solvent in a vial

Other ingredients (inactive ingredients)	water for injections

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

What ADZYNMA looks like

ADZYNMA is supplied as a white to off-white powder in a single-dose glass vial.

Each pack of ADZYNMA contains:

- 1 drug powder vial of ADZYNMA containing 500 IU or 1500 IU rADAMTS13 activity
- 1 solvent vial containing 5 mL water for injections
- 1 reconstitution device (BAXJECT II Hi-Flow)
- 1 disposable syringe (10 mL or 20 mL)
- 1 infusion set (25-gauge)
- 2 alcohol swabs

ADZYNMA is available in:

- ADZYNMA 500 IU - AUST R 469165
- ADZYNMA 1500 IU - AUST R 473505

Not all presentations may be available in Australia.

Who distributes ADZYNMA

ADZYNMA is supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd
Level 39, 225 George Street
Sydney NSW 2000
Australia
Telephone: 1800 012 612
www.takeda.com/en-au

This leaflet was prepared in January 2026.