

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 Cablivi?

Cablivi contains the active ingredient caplacizumab. Cablivi is used to treat an episode of acquired thrombotic thrombocytopenic purpura (aTTP).

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

2. What should I know before I use Cablivi?

Do not use if you have ever had an allergic reaction to caplacizumab 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 Cablivi?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cablivi 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 Cablivi?

- Treatment with Cablivi is started by a doctor experienced in blood disorders, before plasma exchange treatment begins.
- Subsequent doses will be given after each daily plasma exchange and then for at least 30 days after plasma exchange treatment has finished.
- If your doctor decides you or your caregiver can inject Cablivi, they will train you on how to do so safely.

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

5. What should I know while using Cablivi?

Things you should do	<ul style="list-style-type: none">• If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine• Remind any doctor, dentist or pharmacist you visit that you are using Cablivi.
Things you should not do	<ul style="list-style-type: none">• Do not use Cablivi if you think that it has been frozen or exposed to temperatures above 30°C.
Looking after your medicine	<ul style="list-style-type: none">• Before use, keep Cablivi in a refrigerator where the temperature is between 2-8°C.• It may be stored at room temperature up to 25°C for a single period of up to 2 months. Do not return Cablivi to refrigerated storage after storage at room temperature.• Keep Cablivi in the original carton to protect from light.• Do not allow it to freeze. Discard if frozen.

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

6. Are there any side effects?

Serious side effects may include unusual or excessive bleeding events and stroke. Common side effects may include bleeding nose or gums, as well as fever, headache, fatigue or hives.

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.

Cablivi™

Active ingredient: *caplacizumab*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Cablivi?

Cablivi contains the active ingredient **caplacizumab**.

It is used to treat an episode of acquired thrombotic thrombocytopenic purpura (aTTP).

aTTP is a rare blood clotting disorder where blood clots form in small blood vessels. These clots can block blood vessels and damage the brain, heart, kidneys or other organs.

Cablivi prevents the formation of these blood clots by stopping platelets in the blood from clumping together.

It can also reduce the risk of experiencing another episode of aTTP soon after the first.

2. What should I know before I use Cablivi?

Warnings

Do not use Cablivi if:

- you are allergic to caplacizumab, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- you notice any particulate matter or discolouration in the syringe prior to injection.

Check with your doctor if you:

- bleed excessively or experience unusual symptoms such as headache, shortness of breath, tiredness, drop in blood pressure or fainting during treatment. Your doctor may ask you to stop the treatment.
- are using anticoagulants such as Vitamin K antagonists, rivaroxaban, apixaban (which treat blood clots).
- are using anti-platelet agents such as aspirin, or low molecular weight heparin (which prevent blood clots).
- have a bleeding disorder, such as haemophilia.
- have severely reduced liver function.
- are going to have an operation or dental treatment. Your doctor will decide if it can be postponed or if you should stop Cablivi before your surgery or dental treatment.

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

Tell 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 become pregnant while using this medicine, tell your doctor immediately.

Use in children

- There is not enough information to recommend the use of this medicine for children under the age of 18 years.

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 Cablivi and affect how it works:

- medicines used to treat blood clots such as vitamin K antagonists, rivaroxaban, apixaban
- anti-platelet agents, medicines used to prevent blood clots, such as aspirin, low molecular weight heparin.

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

4. How do I use Cablivi?

How much to use

First dose

- The recommended treatment is 1 vial injected into a vein by a healthcare professional. The injection will be given before starting plasma exchange.

Subsequent doses

- The recommended treatment is 1 vial once daily as a subcutaneous injection (under the skin of the belly).

When to use Cablivi

- The injection will be given after each daily plasma exchange for as long as you are having plasma exchange treatment.
- After the daily plasma exchange treatment finishes, your treatment with Cablivi will continue for at least 30 days with injection of 1 vial once daily.
- Your doctor may ask you to continue daily treatment until the underlying signs of your disease are resolved.

How to inject Cablivi

- Treatment with Cablivi is started by a doctor experienced in blood disorders.
- Your doctor may decide that you or your caregiver can inject Cablivi. In this case, your doctor or healthcare provider will train you or your caregiver on how to use Cablivi.
- **Read carefully the "Instructions for Use" leaflet provided in the carton.** If you do not understand the instructions, ask your doctor or pharmacist for help.

If you forget to use Cablivi

Cablivi should be used regularly at the same time each day.

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, inject it as soon as you remember, and then go back to using Cablivi as you would normally.

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

If you use too much Cablivi

If you think that you have used too much Cablivi, 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 Cablivi?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Cablivi.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

Call your doctor straight away if you:

- become pregnant while using this medicine

Remind any doctor, dentist or pharmacist you visit that you are using Cablivi.

Things you should not do

- Do not use Cablivi if you think that it has been frozen or exposed to temperatures above 30°C.
- Do not use Cablivi to treat other complaints.
- Do not give the medicine to anyone else, even if they have the same condition as you
- Do not stop using Cablivi without checking with your doctor.

Looking after your medicine

- Before use, keep Cablivi in a refrigerator where the temperature is between 2-8°C.
- Cablivi may be stored at room temperature up to 25°C for a single period of up to 2 months. Do not return

Cablivi to refrigerated storage after storage at room temperature.

- Keep Cablivi in the original carton to protect from light.
- Do not allow it to freeze. Discard if frozen.

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

Keep it where young children cannot reach it.

When to discard your medicine

After injecting Cablivi, immediately throw away the used pre-filled syringe and vial in a sharps container as instructed by your doctor or pharmacist.

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
Injection site-related: <ul style="list-style-type: none">• redness• rash• itching• bleeding Bleeding-related: <ul style="list-style-type: none">• bleeding gums• nose bleeds Other: <ul style="list-style-type: none">• fever• tiredness• headache• muscle pain• hives	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Bleeding-related: <ul style="list-style-type: none">• bleeding that may be serious or life-threatening• long or excessive bleeding• severe, sudden-onset headache with vomiting, decreased level of consciousness, fever and sometimes seizures and neck stiffness/pain. This could indicate bleeding on the brain.• bleeding from your eye• vomiting blood• blood in the stools	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<ul style="list-style-type: none"> black, tar-like stools bleeding from the stomach bleeding haemorrhoids rectal (back passage) bleeding blood in the urine excessive menstrual bleeding vaginal bleeding coughing blood bruising shortness of breath <p>Other:</p> <ul style="list-style-type: none"> Stroke <p>Allergic reaction-related:</p> <ul style="list-style-type: none"> 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. 	

(AUST R 318058)

Who distributes Cablivi

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

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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 Cablivi contains

Active ingredient (main ingredient)	Caplacizumab 10 mg
Other ingredients (inactive ingredients)	sucrose citric acid sodium citrate dihydrate polysorbate 80

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

What Cablivi looks like

Cablivi is a freeze-dried white powder for reconstitution with diluent for injection. Following reconstitution, the solution is clear, colourless or slightly yellowish.

Cablivi comes in a carton containing:

- 1 vial with caplacizumab powder
- 1 pre-filled syringe with diluent
- 1 vial adaptor
- 1 needle
- 2 alcohol swabs.