

- ▼ 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™

caplacizumab

Consumer Medicine Information

What is in this leaflet

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

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What Cablivi is used for

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. Cablivi therefore reduces the risk of experiencing another episode of aTTP soon after the first.

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.

Cablivi is available only with a doctor's prescription.

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

Before you use Cablivi

When you must not use it

Do not use Cablivi if you have an allergy to:

- any medicine containing caplacizumab
- 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 use Cablivi 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.

Do not use Cablivi if you notice any particulate matter or discolouration prior to administration.

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, or if any of the following apply to you:

- bleeding excessively during treatment. Your doctor may ask you to stop the treatment. The doctor will advise when you can start your treatment again.
- are using anticoagulants such as Vitamin K antagonists, rivaroxaban, apixaban (which treat blood clots). Your doctor will decide how you should be treated.
- are using anti-platelet agents such as aspirin, or low molecular weight heparin (which prevent blood clots). Your doctor will decide how you should be treated.
- have a bleeding disorders, such as haemophilia. Your doctor will decide how you should be treated.
- have severely reduced liver function. Your doctor will decide how you should be treated.
- 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.

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

Your doctor will discuss the risks and benefits of having Cablivi during pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will advise you whether to discontinue breastfeeding or not use Cablivi, considering the benefit of breastfeeding to the baby and the benefit of Cablivi to you.

If you have not told your doctor about any of the above, tell them before you start using Cablivi.

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 Cablivi may interfere with each other. These include:

- 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.

These medicines may be affected by Cablivi or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to use Cablivi

Cablivi comes as a single dose vial for reconstitution with the pre-filled diluent syringe.

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

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.

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). The injection will be given after each daily plasma exchange for as long as you are having plasma exchange treatment.

After the daily plasma 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 use it

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.

How long to use Cablivi

To get the most benefit from your treatment, it is important to use Cablivi as prescribed and for as long as your doctor tells you to use it.

Talk to your doctor before stopping treatment.

Stopping Cablivi too early can cause your condition to come back.

If you forget to use it

If it is less than 12 hours before your next dose, skip the dose you missed and inject 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 that you missed.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, if you

think that you or anyone else may have used too much Cablivi. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Cablivi

Things you must do

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

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

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

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

Things you must 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 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 using Cablivi without checking with your doctor.

Side effects

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

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Contact your doctor immediately if any of the following serious side effects occur:

- long or excessive bleeding
- stroke
- bleeding in the brain, evidenced by severe headache of rapid onset, vomiting, decreased level of consciousness, fever, sometimes seizures and neck stiffness or neck pain.

Your doctor may decide to keep you under closer observation or change your treatment.

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

- bleeding gums
- fever
- tiredness
- muscle pain
- headache
- nose bleeds
- hives
- injection site reactions, such as rash, itching and bleeding.

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- bleeding from your eye
- vomiting blood
- blood in the stools
- black, tarry stools
- bleeding from the stomach
- bleeding haemorrhoids
- rectal bleeding

- blood in the urine
- excessive bleeding during periods
- vaginal bleeding
- coughing blood
- shortness of breath
- bruising.

The above list includes serious side effects that may require medical attention.

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

Other side effects not listed above may also occur in some people.

After using Cablivi

Storage

All medicines should be kept where children cannot reach them.

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.

Disposal

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

If your Doctor tells you to stop using Cablivi 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

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

Cablivi is provided in a carton containing:

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

Ingredients

Cablivi contains 10 mg of caplacizumab as the active ingredient.

Inactive Ingredients:

- sucrose
- citric acid
- sodium citrate dihydrate
- polysorbate 80.

The prefilled diluent syringe contains water for injections.

Supplier

Cablivi is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

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