

Berinert® IV

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.

1. Why am I using Berinert® IV?

Berinert® IV contains the active ingredient, human C1 esterase inhibitor. Berinert® IV is used for the treatment of attacks in people with hereditary angioedema (HAE) (oedema=swelling).

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

2. What should I know before I use Berinert® IV?

Do not use if you have ever had an allergic reaction to Berinert® IV 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, think you are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Berinert® IV and affect how it works.

For more information see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Berinert® IV?

- The recommended dosage is 20 IU per kilogram of body weight.
- Your doctor will prescribe the dosage that should be administered, based on your body weight.
- Training will be provided for preparation and administration of Berinert® IV prior to use.
- If Berinert® IV 500 IU is not injected immediately, it must be stored at 2-8°C and used within 24 hours of reconstitution.
- If Berinert® IV 1500 IU is not injected immediately, it must be stored at 2-8°C and used within 8 hours of reconstitution.

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

5. What should I know while using Berinert® IV?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Berinert® IV.• Notice any signs of serious side effect – this may indicate that the administration of Berinert® IV needs to be stopped immediately.
Things you should not do	<ul style="list-style-type: none">• Do not give or share your medicine with anyone else, even if they have the same condition as you.• Do not mix Berinert® IV with other medicinal products or diluents either before or during administration.
Driving or using machines	<ul style="list-style-type: none">• Make sure you are aware of how Berinert® IV affects you before driving or operating machinery.• Berinert® IV has no or negligible influence on ability to drive and use machines. However, side effects listed in Section 6. Are there any side effects? may impact your ability to drive and use machines.
Looking after your medicine	<ul style="list-style-type: none">• Store Berinert® IV in the carton in a cool, dry place protected from light where the temperature stays below 25°C.• Do not freeze.

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

6. Are there any side effects?

Serious side effects may include irregular or faster heart beat, feeling faint or sick, difficulty in breathing or dizziness. Other common side effects include reactions at the site of the injection, itching, rash, headache, abdominal pain, nausea, muscle spasms, pain, diarrhoea, vomiting and fever.

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.

Beriner[®] IV

Active ingredient(s): Human C1 esterase inhibitor

Consumer Medicine Information (CMI)

This leaflet provides important information about using Beriner[®] IV. **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 Beriner[®] IV.**

Where to find information in this leaflet:

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

1. Why am I using Beriner[®] IV?

Beriner[®] IV contains the human protein C1 esterase inhibitor as the active ingredient. Beriner[®] IV is a product made from human plasma (this is the liquid part of the blood) and is presented as a powder and diluent.

Beriner[®] IV for intravenous (into the vein) injection is used for the treatment of acute attacks in patients with hereditary angioedema (HAE) (oedema – swelling).

HAE is a congenital disease of the vascular system. It is a non-allergic disease. HAE is caused by the deficiency, absence or defective production of C1 esterase inhibitor and is characterised by the following symptoms:

- swelling of the hands and feet that occurs suddenly
- facial swelling with tension sensation that occurs suddenly
- eyelid swelling, lip swelling, possible laryngeal (voice-box) swelling with difficulty in breathing
- tongue swelling
- colic pain in abdominal region.

Generally all parts of the body can be affected.

Beriner[®] IV treats the HAE attack by replacing the missing or malfunctioning C1 esterase inhibitor protein your body needs.

2. What should I know before I use Beriner[®] IV?

Warnings

Do not use Beriner[®] IV if:

- you are allergic to C1 esterase inhibitor, or any of the ingredients listed at the end of this leaflet.

Check with your doctor if you:

- have any other medical conditions (pre-existing blood clotting condition or blood related condition)
- take any medicines for any other condition
- have an allergy to any medicine or food
- are on a sodium controlled diet
- are pregnant, plan to become pregnant or are breastfeeding.

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, think you are pregnant, intend to become pregnant or are breastfeeding.

Beriner[®] IV should only be used if clearly needed during pregnancy or breastfeeding.

Allergies to any medicine or food

If you have allergies, you may be treated with antihistamines and corticosteroids as a preventative measure.

History of blood clotting

There is a potential risk of blood clots forming when higher than recommended doses of Beriner[®] IV are used to treat Capillary Leak Syndrome (outflow of fluid from the small blood vessels into the tissue), which is a non-approved indication.

Tell your doctor if you notice any other effects not listed in Section [6. Are there any side effects?](#)

Virus safety

This product is made from human blood. When products are made from human blood and injected into you, it is possible that viruses or other substances could be present in the product and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or parvovirus B19. There could also be other infectious agents some of which may not have been discovered.

To reduce the risk of this happening extra steps are taken when manufacturing this product. Strict controls are applied when selecting blood donors and donations. The product is specially treated to kill and remove viruses. These special treatments are considered effective against certain viruses known as enveloped viruses (such as HIV

and hepatitis B and C) and also for non-enveloped viruses hepatitis A and parvovirus B19. Despite these measures, the risk of transmitting infection cannot be totally eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Discuss the risk and benefits of this medicine with your doctor.

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 affect the way other medicines work.

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

4. How do I use Berinert® IV?

Berinert® IV is used for intravenous (into the vein) injection.

Treatment should be started and supervised by a doctor. If your doctor decides that you should self-administer Berinert® IV at home or in other appropriate settings, they will ensure you receive detailed instructions and training on how to use it.

Your doctor will also tell you what to do if you experience an HAE attack.

If you do not understand the instructions, ask your doctor.

How much to use

- The recommended dosage is 20 IU per kilogram of body weight.
- Your doctor will prescribe the dosage that you should administer, based on your body weight.
- Follow the instructions provided and use Berinert® IV until your doctor tells you to stop.

When to use Berinert® IV







- Your doctor will discuss with you when Berinert® IV should be used.

How to prepare Berinert® IV for administration

If your doctor considers that you should self-administer Berinert® IV, the instructions below should be followed carefully.

1. Allow the vial of Berinert® IV powder and diluent (Water for Injections) to reach room temperature prior to use.
2. Wash hands with soap and water and dry hands thoroughly with a clean towel.

3. Find a clean, flat working surface such as a table, where you can prepare Berinert® IV undisturbed.
4. Thoroughly clean the preparation area with disinfectant wipes.
5. Open the carton and take out the Mix2Vial™ filter transfer set. The Mix2Vial™ filter transfer set is intended to filter the contents of a single vial of Berinert® IV only. If multiple vials of Berinert® IV are to be given, a separate Mix2Vial™ must be used for each vial.
6. Remove protective caps from both the product and diluent vials.
7. Wipe the rubber stoppers of both the product and diluent vials with one of the alcohol swabs provided in the administration pack and allow to dry for two minutes. Do not leave the alcohol swab resting on the stoppers. Do not touch the rubber stoppers with your fingers.


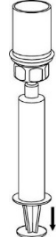

<p>8. Open the Mix2Vial™ package by peeling away the lid. Do not remove the Mix2Vial™ from the blister package.</p>	
<p>9. Place the diluent vial on a flat surface and hold the vial firmly. Take the Mix2Vial™ together with the package and push the blue end straight down through the diluent stopper.</p>	
<p>10. Carefully remove the package from the Mix2Vial™ set. Make sure that you only pull up the package and not the Mix2Vial™ itself.</p>	
<p>11. Place the product vial on an <u>even and firm surface</u>. Invert the diluent vial with the Mix2Vial™ set attached and push the transparent adapter straight down through the product vial stopper. The diluent will automatically flow into the product vial.</p>	
<p>12. With one hand, hold the product side of the Mix2Vial™ set, hold the diluent side with the other hand and unscrew the set counterclockwise into two pieces. Discard the diluent vial with the blue part attached.</p>	
<p>13. Gently swirl the product vial until the substance is fully dissolved. Do not shake as this could damage the product. The 500 IU solution should be clear and colourless.</p>	

<p>The 1500 IU solution should be clear and colourless to slightly opalescent. It might sparkle when held up to the light but must not contain any obvious particles.</p> <p>Do not use solutions that are cloudy or contain flakes or particles.</p> <p>This medicine does not contain an antimicrobial preservative.</p>	
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If the 500 IU solution is not injected immediately it must be stored at 2-8°C and used within 24 hours of preparation.

If the 1500 IU solution is not injected immediately it must be stored at 2-8°C and used within 8 hours of preparation.

The reconstituted product should only be stored in the vial. Allow the solution to reach room temperature before use.

<p>14. Draw air into an empty, sterile, syringe. Use the syringe provided with the product. While the product vial is upright, connect the syringe to the Mix2Vial™'s Luer Lock fitting by screwing clockwise. Inject air into the product vial.</p>	
<p>15. While keeping the syringe plunger pressed, invert the product vial and draw the solution into the syringe by slowly pulling the plunger back.</p>	
<p>16. When the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe in one hand, and with the other hand disconnect the Mix2Vial™ set and product vial from the syringe by unscrewing counterclockwise.</p>	

If the same patient is to receive more than one vial, the contents of multiple vials may be pooled in a single administration device (e.g. syringe). A new unused Mix2Vial™ transfer set should be used for each Berinert® IV vial.

How to administer Berinert® IV

Your doctor or nurse will instruct you on how to administer Berinert® IV yourself if you need to treat yourself at home or in other appropriate settings.

It is important that Berinert® IV is injected directly into a visible vein. Do not inject into surrounding tissues or into an artery. Once you learn how to self-administer, follow the instructions provided below.

1. Assemble supplies

Gather the syringe filled with Berinert® IV, the remaining items in the administration pack (an infusion set and an alcohol swab) and the following supplies (not provided with Berinert® IV):

- tourniquet
- sterile gauze and tape, or transparent dressing
- gloves (if recommended by your healthcare provider)
- disinfectant wipes
- sharps or other container.

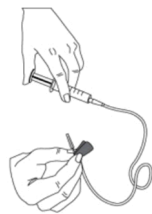



You may also need a treatment diary or log book as instructed by your doctor or nurse.

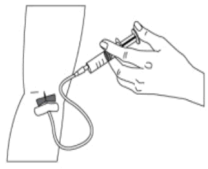
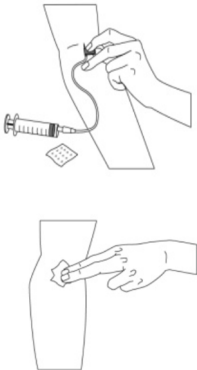
2. Wash hands

- Thoroughly wash and dry your hands
- If you have been told to wear gloves when preparing your infusion, put the gloves on.

3. Clean surface

- Thoroughly clean a table or other flat surface using the disinfectant wipes.

<p>4. Prime the infusion set</p> <p>As instructed by your healthcare provider, to prime (fill) the infusion tubing, connect the syringe filled with Berinert® IV to the infusion set tubing and gently push on the syringe plunger to fill the tubing with Berinert® IV.</p>	
<p>5. Prepare the infusion site</p> <p>Apply a tourniquet above the site of the infusion.</p> <p>Prepare the infusion site by wiping the skin well with an alcohol swab and allow it to dry.</p>	
<p>6. Infusion</p> <p>As instructed by your healthcare provider, insert the butterfly needle of the infusion set tubing into your vein</p>	
<p>If necessary, use sterile gauze and tape or transparent dressing to hold the needle in place.</p> <p>To make sure that the needle is in a vein, gently pull back on the syringe plunger and check to see if blood is in the tubing.</p> <p>If there is blood present, then the needle is in a vein.</p> <p>If there is no blood present, remove the needle and repeat this step using a new needle,</p>	

<p>new administration tubing, and a different injection site. Remove the tourniquet.</p>	
<p>Inject the Berinert® IV 500 IU solution by slow intravenous injection at a rate of approximately 4 mL per minute. Inject the Berinert® IV 1500 IU solution as a bolus intravenous injection.</p>	
<p>7. Clean Up After infusing the entire amount of Berinert® IV, remove the infusion set and cover the infusion site with a bandage, holding pressure on the site for a few minutes. Dispose of all unused solution, the empty vials, and the used needles and syringe in an appropriate container used for throwing away waste that might hurt others if not handled properly.</p>	

8. Record treatment

- It is recommended that treatment details and lot number from the Berinert® IV vial label are recorded every time you use Berinert® IV.

Do not mix Berinert® IV with other medicinal products or diluents either before or during administration.

If you forget to use Berinert® IV

Berinert® IV should be used as prescribed by your doctor. If you miss a dose, follow your doctor's instructions or contact your doctor or pharmacist.

If you use too much Berinert® IV

No symptoms of overdose with Berinert® IV are known. No cases of overdose have been reported. If you think that you have used too much Berinert® IV,

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor.

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

5. What should I know while using Berinert® IV?

Things you should do

Call your doctor straight away if you:

- Notice signs of a side effect. A serious side effect may indicate that the use of Berinert® IV needs to be stopped immediately.

Remind any doctor, dentist or pharmacist you visit that you are using Berinert® IV.

Use this medicine in one patient on one occasion only.

Things you should not do

- Do not give or share your medicine with anyone else, even if they have the same condition as you.
- Do not mix Berinert® IV with other medicinal products or diluents either before or during administration.
- Stop using this medicine suddenly unless instructed by your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Berinert® IV affects you.

Berinert® IV has no or negligible influence on ability to drive and use machines. However, side effects listed in Section 6. [Are there any side effects?](#) may impact your ability to drive and use machines.

Looking after your medicine

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

Store Berinert® IV in the outer carton in a cool, dry place protected from light where the temperature stays below 25°C.

Do not freeze.

Keep it out of the sight and reach of children.

Disposal of your medicine

Do not use Berinert® IV after the expiry date detailed on the carton packaging.

The reconstituted medicine should only be stored in the vial at 2-8°C if it is not administered immediately.

Dispose of Berinert® IV 500 IU if it is not administered within 24 hours of reconstitution.

Dispose of Berinert® IV 1500 IU if it is not administered within 8 hours of reconstitution.

If your doctor tells you to stop using Berinert® IV or the pack has expired, ask them what to do if you have a pack left over.

Getting rid of any unwanted medicine

Any unused portion remaining in the vial must be discarded appropriately.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">nausea or vomitingmuscle spasmsabdominal paingeneral paindiarrhoeaheadachechills and feverpain and redness where the injection was givenabnormal taste.	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
<ul style="list-style-type: none">irregular or faster heart beatfeeling faint (fall in blood pressure)reddening of the skinrashdifficulty in breathingdizzinessfeeling sick	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.

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 Berinert® IV contains

Active ingredient (main ingredient)	Human C1 esterase inhibitor
Other ingredients (inactive ingredients)	Glycine Sodium chloride Sodium citrate

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

What Berinert® IV looks like

Berinert® IV is a white powder contained in a glass vial.

The 500 IU vial of Berinert® IV comes in a pack containing:

- a vial of diluent (10 mL of Water for Injections) used to dissolve the powder
- a Mix2Vial™ filter transfer set
- an administration pack with:
 - a disposable 10 mL syringe
 - an infusion set
 - 2 alcohol swabs.

The 1500 IU vial of Berinert® IV comes in a pack containing:

- a vial of diluent (3 mL of Water for Injections) used to dissolve the powder
- a Mix2Vial™ filter transfer set
- an administration pack with:
 - a disposable 5 mL syringe
 - an infusion set
 - 2 alcohol swabs.

500 IU: AUST R 157279

1500 IU: AUST R 281469

Who distributes Berinert® IV

Berinert® IV is supplied in Australia by

CSL Behring (Australia) Pty Ltd

ABN 48 160 734 761

189-209 Camp Road

Broadmeadows VIC 3047

Australia

For Medical/Technical Enquiries

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