Berinert® IV

Human C1 esterase inhibitor

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Berinert® IV.

It does not contain all the available information. If you require further information about this medicine or your treatment generally, or if you have any questions or are not sure about something in this leaflet, consult your doctor.

All medicines have benefits and risks. Your doctor has weighed the benefits that Berinert® IV will have for you against the risks.

If you have any concerns about taking this medicine, ask your doctor. Follow your doctor's advice even if it is different from what this leaflet says.

Keep this leaflet with the medicine.

You may need to read it again.

The information in this leaflet is subject to change.

Please check with your doctor whether there is any new information about this medicine that you should know since you were last treated.

What Berinert® IV is used for

This medicine is used for the treatment of attacks in people 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 deficiency, absence or defective production of C1 esterase inhibitor, an important protein. The illness 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, possibly laryngeal (voice-box) swelling with difficulty in breathing
- tongue swelling
- colic pain in abdominal region.

Generally all parts of the body can be affected.

Ask your doctor if you have any questions about why Berinert® IV has been prescribed for you.

How Berinert® IV works

This product is made from human plasma (this is the liquid part of the blood). It contains the human protein C1 esterase inhibitor as the active ingredient. It treats the HAE attack by replacing the missing or malfunctioning C1 esterase inhibitor protein your body needs.

Berinert® IV is available as a 500 IU strength and a 1500 IU strength.

Before you are given Berinert® IV

When you must not have it

Do not have Berinert® IV if you are allergic to:

- protein C1 esterase inhibitor
- any of the ingredients listed at the end of this leaflet.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you are pregnant or breast feeding.

This medicine should only be used if clearly needed during pregnancy or breast feeding.

Tell your doctor if you are on a controlled sodium diet.

This medicine contains sodium which should be taken into consideration.

Tell your doctor if you are allergic to any medicine or food.

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

If you suffer from laryngeal swelling (laryngeal oedema), due to the location of the attack and risk of suffocation due to decreased air entry, you should be carefully monitored in hospital.

If you have not told your doctor about any of the above, tell them before you are given Berinert® IV.

Your doctor can discuss with you the risks and benefits involved with using this medicine.

About blood products

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 yet 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.

Please discuss the risks and benefits of this medicine with your doctor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work.

How to use Berinert® IV

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.

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

How much is given

The dosage is 20 IU per kilogram of body weight.

When it is given

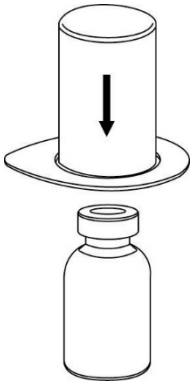
Your doctor will discuss with you when you should be given Berinert® IV.

How to prepare it

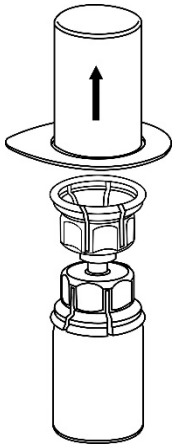
If your doctor considers that you should self-administer Berinert® IV, the instructions below should be followed carefully.

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.
8. Open the Mix2Vial™ package by peeling away the lid.

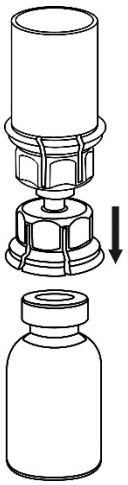
9. Place the diluent vial on a flat surface and hold the vial firmly. Take the Mix2Vial™ together with the package and push the blue end straight down through the diluent stopper.



10. Carefully remove the package from the Mix2Vial™ set. Make sure that you only pull up the package and not the Mix2Vial™ itself.



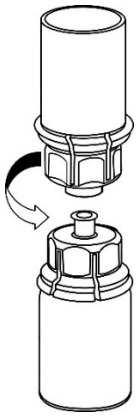
11. Place the product vial on an even and firm surface. Invert the diluent vial with the Mix2Vial™ set attached and push the transparent adapter straight down through the product vial stopper. The diluent will automatically flow into the product vial.



Berinert® IV 500 IU is reconstituted (mixed) with 10 mL of diluent.

Berinert® IV 1500 IU is reconstituted with 3 mL of diluent.

12. With one hand hold the product side of the Mix2Vial™ set, hold the diluent side with the other hand and unscrew the set into two pieces. Discard the diluent vial with the blue part attached.



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.

    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.

Do not use solutions that are cloudy or contain flakes or particles.

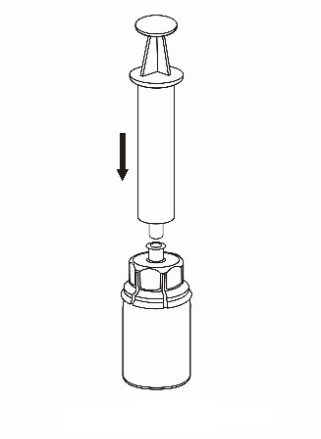
This medicine does not contain an antimicrobial preservative.

If the 500 IU solution is not injected immediately it must be stored at 2–8°C and used within 24 hours of preparation.

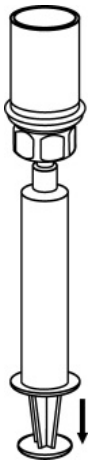
If the 1500 IU solution is not injected immediately, it must be stored at 2–8°C and used within 8 hours of preparation.

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

14. Draw air into an empty, sterile, syringe. Use the syringe provided with the product or a silicone-free syringe. While the product vial is upright, connect the syringe to the Mix2Vial™'s Luer lock fitting. Inject air into the product vial.



15. While keeping the syringe plunger pressed, invert the product vial and draw the solution into the syringe by slowly pulling the plunger back.



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.
    Attach the syringe to a suitable intravenous (IV) administration set.

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 inject Berinert® IV

Your doctor or nurse will instruct you on how to inject 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, an alcohol swab and a plaster) 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 healthcare provider.

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.

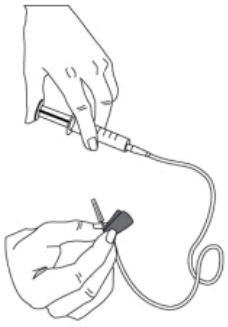
3. Clean surface

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

4. Prime the infusion set

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.



5. Prepare the infusion site

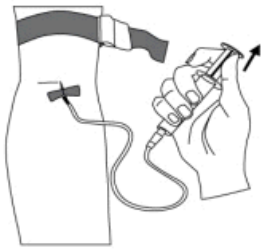
- Apply a tourniquet above the site of the infusion
- Prepare the infusion site by wiping the skin well with an alcohol swab and allow it to dry.

6. Infusion

As instructed by your healthcare provider:

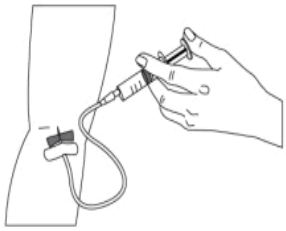
- Insert the butterfly needle of the infusion set tubing into your vein

- If necessary, use sterile gauze and tape or transparent dressing to hold the needle in place
- 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



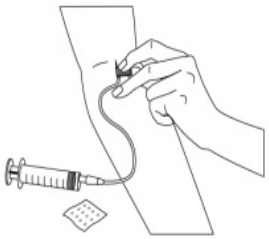
- If there is blood present, then the needle is in a vein. If there is no blood present, remove the needle and repeat this step using a new needle, new administration tubing, and a different injection site
- Remove the tourniquet
- Inject the Berinert® IV 500 IU solution by slow intravenous injection at a rate of approximately 4 mL per minute.

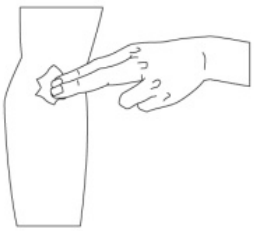
  Inject the Berinert® IV 1500 IU solution as a bolus intravenous injection.



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.

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 too much is given (overdose)

No symptoms of overdose with Berinert® IV are known.

If you have any questions consult your doctor.

While you are having Berinert® IV

Things you must do

If you notice signs or symptoms of a serious allergy or anaphylaxis (see Side effects) while you are being given Berinert® IV tell your doctor immediately as the administration of Berinert® IV should be stopped immediately.

Things you must not do

Do not give or share your medicine with anyone else, even if they have the same condition as you.

Use this medicine in one patient on one occasion only.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given Berinert® IV.

This medicine helps most people with HAE who suffer an attack but it may have unwanted

side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor immediately if you notice any of the following symptoms which may be signs of a serious allergy or anaphylaxis as the injection of Berinert® IV should be stopped:

- irregular or faster heart beat
- feeling faint (fall in blood pressure)
- reddening of the skin
- rash
- difficulty in breathing
- dizziness
- feeling sick.

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

- nausea or vomiting
- muscle spasms
- abdominal pain
- general pain
- diarrhoea
- headache
- chills and fever
- pain and redness where the injection was given
- abnormal taste.

These are the more common side effects of Berinert® IV and occur very rarely.

There is a potential risk of blood clots forming when higher than recommended doses of Berinert® 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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects.

This medicine does not generally cause any undesired reactions.

Storing Berinert® IV

Keep Berinert® IV in a cool dry place where the temperature stays below 25°C. Do not freeze.

Keep the product in the carton in order to protect it from light.

Do not use after the expiry date.

Keep it out of the sight and reach of children.

Disposal

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.

Product description

What it looks like

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

Berinert® IV comes in the following dose strengths:

- 500 IU
- 1500 IU

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
  - alcohol swabs
  - a plaster (adhesive bandage).

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
  - alcohol swabs
  - a plaster (adhesive bandage).

Ingredients

Berinert® IV contains human C1 esterase inhibitor as the active ingredient.

It also contains:

- glycine
- sodium chloride
- sodium citrate.

Distributor

CSL Behring (Australia) Pty Ltd
ABN 48 160 734 761
189–209 Camp Road
Broadmeadows VIC 3047
Australia

Manufacturer

Berinert® IV is manufactured by CSL Behring GmbH, Germany

Date of most recent amendment

February 2019

Australian Register Numbers
500 IU: AUST R 157279
1500 IU: AUST R 281469