

Hizentra® AU

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 Hizentra® AU?

Hizentra® AU contains the active ingredient human normal immunoglobulin. Hizentra® AU is used for the replacement of antibodies because your antibody levels are low (referred to as immunodeficiency), or for a condition where there is an imbalance in your immune system requiring treatment with immunoglobulins (referred to as immunomodulation).

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

2. What should I know before I use Hizentra® AU?

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

3. What if I am taking other medicines?

Some medicines may interfere with Hizentra® AU 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 Hizentra® AU?

- Your doctor will determine the dose of Hizentra® AU that you will receive.
- Doses may be given at repeated intervals, from daily to once every two weeks.

Your doctor may adjust the dose based on your response to the treatment. More instructions can be found in Section [4. How do I use Hizentra® AU?](#) in the full CMI.

5. What should I know while using Hizentra® AU?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Hizentra® AU.
Things you should not do	<ul style="list-style-type: none">• Do not change the dose or dosing interval without consulting with your doctor.
Driving or using machines	<ul style="list-style-type: none">• This medicine is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Do not freeze. Keep the vial in the outer carton in order to protect from light.• Do not use this medicine after the expiry date.

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

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. The most common side effects are swelling, pain, redness or itching where the infusion was given. The more serious side effects include reduced urination, severe headache, neck stiffness, inability to stand bright light, painful eye movements, pain/tenderness or swelling/dischouration of an arm or leg, tingling, numbness or weakness on one side of the body, shortness of breath, chest pain, fever or an allergic reaction.

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.

Hizentra[®] AU

Active ingredient: *Human normal immunoglobulin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Hizentra[®] AU. **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 Hizentra[®] AU.**

Where to find information in this leaflet:

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

1. Why am I using Hizentra[®] AU?

Hizentra[®] AU contains the active ingredient human normal immunoglobulin and is manufactured from human plasma (the liquid component of blood) collected by Australian Red Cross Lifeblood.

Immunoglobulins are also known as antibodies and are blood proteins that help your body to fight infections.

Immunoglobulins are produced by your body's immune system to fight infections caused by bacteria and viruses.

Hizentra[®] AU is used:

- for the replacement of antibodies because your antibody levels are low (referred to as immunodeficiency), or
- for a condition where there is an imbalance in your immune system requiring treatment with immunoglobulins (referred to as immunomodulation).

2. What should I know before I use Hizentra[®] AU?

Warnings

Do not use Hizentra[®] AU if:

- you have a history of allergy to human immunoglobulin products (allergic reactions may include skin rash, face swelling, wheezing or breathing difficulties), or previously been told you react to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have been told you have antibodies to immunoglobulin A (IgA)

- you suffer from hyperprolinaemia type I or II (a genetic disorder causing high levels of the amino acid proline in the blood)

Check with your doctor if you:

- are receiving Hizentra[®] AU or this type of medicine (a human normal immunoglobulin) for the first time or after a long break in treatment (e.g. several months), or if you have been switched from another human normal immunoglobulin medicine
- have a history of heart, or blood vessel disease, or blood clots, have thick blood, have been immobile for some time. Also tell the doctor what medicine you are using as some medicines, such as those that contain the hormone estrogen (for example, birth control pills), may increase your risk of developing a blood clot.
- have low blood volume (hypovolaemia)
- have IgA deficiency
- have frequent headaches or migraine
- are over 65 years of age
- have any allergies to any medicines, foods, preservatives or dyes.

Vaccinations

Please inform your doctor if you have had any vaccinations within the last two weeks or are planning to have a vaccination. Hizentra[®] AU may impair the effect of some virus vaccines such as measles, mumps, rubella and varicella for a period of at least 6 weeks, and up to 3 months. After receiving this medicine, a period of 3 months should be allowed before vaccination with some virus vaccines. In the case of measles vaccine, this effect may last for up to 1 year, so if you are going to receive a measles vaccine you should have your measles antibody status checked.

Tell your vaccinating doctor about your treatment with Hizentra[®] AU before receiving any vaccination.

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 or intend to become pregnant.

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

Virus safety

Hizentra[®] AU is made from human plasma (the liquid component of blood). When medicines are made from human blood or plasma, processes are used to prevent

infections being passed from the blood/plasma donor to the person receiving the medicine.

These processes include careful selection of the people who donate blood and plasma to make sure that those who might be carrying infections are excluded. In addition, each donation and pools of donations are tested for indicators of virus/virus infection(s).

Manufacturers of these medicines also include steps in the processing of blood or plasma that inactivate or remove viruses. Despite these processes, when medicines are prepared from human blood or plasma, the possibility of passing on an infection cannot be totally ruled out. Unknown or new viruses or other types of infection could also be passed on.

However, the measures taken in the manufacture of this medicine are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus, and for the non-enveloped viruses hepatitis A (HAV) and B19 virus (B19V).

There is reassuring clinical experience regarding the lack of HAV or B19V infections with immunoglobulins. It is assumed that the antibodies which are in the immunoglobulin product make an important contribution to the viral safety.

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 Hizentra® AU and affect how it works.

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

4. How do I use Hizentra® AU?

How much to use

- Treatment should be started and supervised by a doctor. Hizentra® AU is administered as an infusion subcutaneously (under the skin). If your doctor decides that you should receive Hizentra® AU at home, they will ensure you receive detailed instructions and training on how to use it.
- Your doctor will determine the dose of Hizentra® AU that you will receive. Doses may be given at repeated intervals, from daily to once every two weeks. Your doctor may adjust the dose based on your response to the treatment.

When to use Hizentra® AU

- Your doctor will discuss with you when Hizentra® AU should be used.

How to prepare Hizentra® AU for administration

If your doctor considers that you should receive Hizentra® AU at home, the instructions below should be followed carefully.

Step 1: Clean surface

Clean a table or other flat surface.

Step 2: Assemble supplies

Gather the Hizentra® AU vial(s) and the following supplies (not provided with Hizentra® AU), as directed by your doctor. The Hizentra® AU vials must be at room temperature before administration.

- Administration tubing
- Subcutaneous needle and required tubing
- Syringes
- Transfer device or drawing up needle(s)
- Gauze and tape, or transparent dressing (if required)
- Infusion pump (if required)
- Sharps container
- Alcohol (antiseptic) wipes
- Treatment diary.

Step 3: Wash hands

Thoroughly wash and dry your hands (**Figure 1**).



Figure 1

Step 4: Check vials

Inspect the protective cap of the vials (**Figure 2**).

Hizentra® AU is a pale-yellow to light-brown clear solution. Check for particles or colour changes.



Figure 2

Do not use the vial if:

- the liquid looks cloudy, contains particles, or has changed colour.
- the protective cap of the vial is missing or defective.
- the expiry date on the label has passed.

Step 5: Preparation of Hizentra® AU for infusion

Transfer Hizentra® AU from vial(s) to syringe

Take the protective cap off the vial (**Figure 3**).



Figure 3

Clean the vial stopper with an alcohol wipe (**Figure 4**). Allow to dry.



Figure 4

Attach a needle or transfer device to the syringe tip, using a clean (non-touch) technique. If using a transfer device, follow the instructions provided by the device manufacturer. If using a needle and a syringe to transfer Hizentra® AU, follow the instructions below.

- Attach a sterile transfer needle to a sterile syringe (**Figure 5**).
- Pull out the plunger of the syringe to fill the syringe with air. Make sure the amount of air is the same as the amount of Hizentra® AU you will transfer from the vial.
- Put the Hizentra® AU vial on a flat surface. Keeping the vial upright, insert the transfer needle into the centre of the rubber stopper.
- Check that the tip of the needle is not in the liquid. Then, push the plunger of the syringe down. This will inject the air from the syringe into the airspace of the vial.



Figure 5

- Leaving the needle in the stopper while keeping pressure on the syringe plunger, carefully turn the vial upside down (**Figure 6**).



Figure 6

- Gently withdraw the needle so the tip sits in the Hizentra® AU fluid and release the pressure on the plunger. The fluid will automatically fill the syringe. Once the automatic filling is complete slowly pull back on the plunger to fill the syringe with any remaining Hizentra® AU.
- Take the filled syringe and needle out of the stopper. Take off the needle and throw it away in the sharps container.
- When using multiple vials to achieve the desired dose, repeat this step.

Step 6: Prepare the Subcutaneous needles and related tubing

Attach the subcutaneous needle to infusion tubing (if required).

Prime (fill) the infusion tubing. To prime the tubing, connect the syringe filled with Hizentra® AU to the infusion tubing and gently push on the syringe plunger to fill the tubing with Hizentra® AU (**Figure 7**).



Figure 7

Stop priming before Hizentra® AU fluid reaches the needle.

Step 7: Prepare infusion site(s)

Select an area on your abdomen, thigh, upper arm, or side of upper leg/hip area for the infusion (**Figure 8**).

Never infuse into areas where the skin is tender, bruised, red, or hard. Avoid infusing into scars or stretch marks.

The number of infusion sites depends on the volume of the total dose. Your healthcare professional can advise you about this.

If you are using more than one infusion site, be sure each site is at least 5 cm apart.

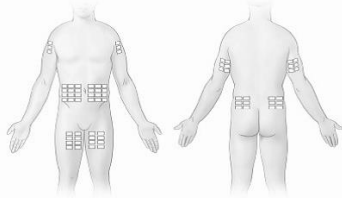


Figure 8



Figure 9

Clean the skin at each site with an alcohol wipe (Figure 9). Let the skin dry.

Step 8: Insert needle(s)

Using two fingers, pinch the skin around the infusion site. Insert the needle into the skin (Figure 10). Your healthcare professional will advise you on the positioning of the needle as it is dependent on the type of needle used.



Figure 10

Secure the needle in place as directed by your healthcare professional (Figure 11). This will keep the needle from coming out

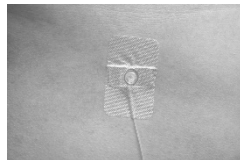


Figure 11

Step 9: Start infusion

MAKE SURE YOU ARE NOT INFUSING HIZENTRA® AU INTO A BLOOD VESSEL. To test for this, pull the plunger back gently. If you see any blood flowing back into the tubing, remove the needle. Discard the tubing and needle and restart from Step 6.

If using an infusion pump, prepare the pump following the manufacturer's instructions.

Follow the instructions that you have been given by your healthcare professional to start the infusion. Infuse at the rate you have been instructed (Figure 12).



Figure 12

Step 10: Record treatment

Complete your treatment diary as instructed by your healthcare professional.

Step 11: Clean up

Remove the needle set and cover the infusion site with a protective dressing as directed by your healthcare professional.

Discard the empty Hizentra® AU vial(s), needles, infusion tubing, and syringes as directed by your healthcare professional (Figure 13).

General rubbish such as packaging can be discarded in the general waste.

If using an infusion pump, clean and store it, following the manufacturer's instructions.



Figure 13

If you forget to use Hizentra® AU

If you think you have missed a dose, speak to your doctor as soon as possible.

If you use too much Hizentra® AU

The effects of an overdose of Hizentra® AU are not known.

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 Hizentra® AU?

Things you should do

Tell your doctor if you are planning to travel overseas.

It is important to obtain a written statement from your doctor explaining the reasons why you need to have this medicine and infusion devices with you, otherwise you may not be allowed to bring it into the country of travel.

Please ensure you have multiple copies of the letter if travelling to more than one country.

Call your doctor straight away if you:

- become pregnant while using this medicine.
- are about to have any blood test. Hizentra® AU may interfere with the results of some tests, resulting in misleading results for some things.

Remind any doctor, dentist or pharmacist you visit that you are using Hizentra® AU.

Things you should not do

- Do not change the dose or dosing interval without consulting with your doctor. If you think you should

receive Hizentra® AU more or less frequently, please speak to your doctor.

Driving or using machines

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

Hizentra® AU is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

- Store below 25°C. Do not freeze.
- Keep the vial in the outer carton in order to protect from light.

Keep it where young children cannot reach it.

When to discard your medicine

Hizentra® AU does not contain any preservatives, so any unused portion should be discarded immediately.

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
<ul style="list-style-type: none"> • swelling, pain, redness or itching where the infusion was given • headache/migraine • nausea or vomiting • pain (including pain in the chest, back, joints, arms, legs) • muscle pain • fatigue • diarrhoea • abdominal pain • fever or chills • feeling faint, dizzy or light headed (fall in blood pressure) • infusion site ulcer. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • reduced urination • severe headache • neck stiffness • inability to stand bright light • painful eye movements 	<p>Call your doctor straight away, or go straight to the</p>

<ul style="list-style-type: none"> • pain/tenderness, swelling/discolouration of an arm or leg • tingling, numbness or weakness on one side of the body • shortness of breath • chest pain • fever • allergic or anaphylactic reaction, symptoms of which may include: <ul style="list-style-type: none"> • swelling of the lips, tongue or eyes • loss of consciousness • hives • difficulty in breathing. 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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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 Hizentra® AU contains

Active ingredient (main ingredient)	Human normal immunoglobulin
Other ingredients (inactive ingredients)	Proline Polysorbate 80 Water

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

What Hizentra® AU looks like

Hizentra® AU is a clear and colourless or pale-yellow to light-brown solution.

Hizentra® AU is packaged using latex free materials.

1 g in a 5 mL solution: AUST R 328606

2 g in a 10 mL solution: AUST R 328607

4 g in a 20 mL solution: AUST R 328608

Who distributes Hizentra® AU

Sponsor

CSL Behring (Australia) Pty Ltd

ABN 48 160 734 761

189–209 Camp Road

Broadmeadows VIC 3047

Australia

Distributor

Australian Red Cross Lifeblood

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