

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 Privigen®?

Privigen® contains the active ingredient human normal immunoglobulin. Privigen® 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 Privigen®?](#) in the full CMI.

2. What should I know before I use Privigen®?

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

3. What if I am taking other medicines?

Some medicines may interfere with Privigen® 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 Privigen®?

- It is usually administered by your doctor or healthcare professional.
- Your doctor will calculate the correct dose for you.

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

5. What should I know while using Privigen®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Privigen®.• If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine. It may affect other medicines used during your surgery.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none">• Patients may experience effects, such as dizziness or nausea, during treatment with Privigen® that might affect the ability to drive and use machines.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Do not freeze. Keep the bottle 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 Privigen®?](#) 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.

Side effects tend to be related to the rate of infusion and are likely to occur during the first hour of infusion.

If a side effect occurs, the nurse or doctor may reduce the rate of infusion or the infusion may be stopped.

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.

Privigen®

Active ingredient: *Human normal immunoglobulin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Privigen®. **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 Privigen®.**

Where to find information in this leaflet:

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

1. Why am I using Privigen®?

Privigen® contains the active ingredient human normal immunoglobulin.

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.

Privigen® 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 Privigen®?

Warnings

Do not use Privigen®:

- 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.
- if you have been told you have antibodies to immunoglobulin A (IgA)

Check with your doctor if you:

- are receiving Privigen® 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
- suffer from hyperprolinaemia type I or II (a genetic disorder causing high levels of the amino acid proline in the blood)
- have diabetes
- 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 kidney problems or kidney disease
- have high blood pressure
- have low blood volume (hypovolaemia)
- have a condition that causes low antibody levels in your blood (IgA deficiency, hypogammaglobulinaemia or agammaglobulinaemia with or without IgA deficiency)
- have recurrent temporary non-infectious meningitis with intravenous immunoglobulin treatments. If you have a recurrence of aseptic meningitis with intravenous immunoglobulin treatment, your doctor will ask you about the emergence or worsening of your symptoms which may progress to swelling of the brain (brain oedema).
- have frequent headaches or migraine
- have blood group A, B or AB
- are overweight
- are over 65 years of age
- take medicines that may harm your kidneys (nephrotoxic medicines)
- have any allergies to any medicines, foods, preservatives or dyes.

Vaccinations

Please inform your doctor if you are planning to have a vaccination. Privigen® 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 Privigen® 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

Privigen® 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 Privigen® 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 Privigen®.

4. How do I use Privigen®?

How much to use

- **Privigen® is usually administered by your doctor or healthcare professional.**
Privigen® is intended solely for infusion into a vein. Your doctor will calculate the correct dose for you.

This will depend on your illness, your present condition and your weight. On the day of your infusion make sure you have had sufficient fluids which will help reduce the risk of side effects. At the beginning of the infusion you will receive Privigen® at a slow infusion rate. If you tolerate this well, your doctor can gradually increase the infusion rate.

When to use Privigen®

- Privigen® is given to you under the supervision of your doctor or trained medical professional.
- If you think you should receive Privigen® more or less frequently, please speak to your doctor.

Record of use

- It is recommended that every time you receive a dose of Privigen® the name and batch number of the product are recorded in order to maintain a record of the batches used.

If you forget to use Privigen®

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

If you use too much Privigen®

If you think you have had too much Privigen®, speak to your doctor as soon as possible.

As Privigen® is given to you under the supervision of your doctor or trained medical professional, it is very unlikely that you will receive an overdose. If you experience any side effects, tell your doctor immediately.

5. What should I know while using Privigen®?

Things you should do

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine. It may affect other medicines used during your surgery.

Call your doctor straight away if you:

- become pregnant while receiving this medicine.
- are about to have any blood test. Privigen® may interfere with some blood tests. After infusion of this medicine you will have high antibody levels in your blood that may change the results of your blood tests.

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

Things you should not do

- Do not stop using this medicine suddenly.

Driving or using machines

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

Patients may experience effects, such as dizziness or nausea, during treatment with Privigen® that might affect the ability to drive and use machines. If this happens, you

should not drive or use machines until these effects have disappeared.

Looking after your medicine

You will be given this medicine in hospital. You will probably not need to keep any bottles of Privigen® at home. However, if you have to keep this medicine at home:

- Privigen® should be administered as soon as possible after opening the bottle as the solution contains no preservative.
- Store below 25°C. Do not freeze.
- Do not shake.
- Keep the bottle in the outer carton in order to protect from light.

Keep it where young children cannot reach it.

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.

Individuals may react differently to similar doses of the same product. This applies to Privigen®. Side effects tend to be related to the rate of infusion and are likely to occur during the first hour of infusion.

If a side effect occurs, the nurse or doctor may reduce the rate of infusion or the infusion may be stopped.

If you are over 65 years of age you may have an increased chance of getting side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • headache • chills • fever • flu-like illness (including sore throat, blistering or tightness of the throat) • vomiting • difficulty breathing, tissue swelling and skin rash (allergic reactions) • nausea • pain in a joint or muscle • fainting, dizziness and light-headedness (low blood pressure) • paleness of skin • abdominal pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • pain, e.g. infusion site • skin peeling and redness • flushing (including hot flush) • diarrhoea • weakness/tiredness • tremor. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • pain/tenderness, swelling/discolouration of an arm or leg • weakness, or numbness on one or both sides of the body • shortness of breath • chest pain • feeling very tired • skin becoming yellow • dark urine • decreased urine • decreased alertness or difficulty in speaking • palpitations/increased heart rate. 	<p>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.</p>

In rare cases this type of medicine may cause a sudden fall in blood pressure or a condition called anaphylactic shock, which is an allergic reaction that has symptoms such as low blood pressure (feeling faint) and difficulty breathing.

Severe headache, neck stiffness, drowsiness, fever, increased light sensitivity of the eye (photophobia), nausea, and vomiting may occasionally occur after receiving Privigen®.

Rarely, severe breathing problems, light-headedness, drops in blood pressure and fever may occur 1 to 6 hours after receiving this medicine.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

This medicine may affect your blood cell count or liver enzyme levels.

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 Privigen® contains

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

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

What Privigen® looks like

Privigen® is a clear, colourless or pale yellow liquid.

5 g in a 50 mL solution: AUST R 143273

10 g in a 100 mL solution: AUST R 143337

20 g in a 200 mL solution: AUST R 143368

40 g in a 400 mL solution: AUST R 219160

Who distributes Privigen®

Privigen® 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

TOLL FREE: 1800 642 865

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