

Privigen[®]

Normal immunoglobulin (Human) 10% (100 g/L), intravenous infusion.

Consumer Medicine Information

What is in this leaflet

This leaflet contains answers to some common questions about Privigen[®]. It does not contain all the available information about Privigen[®]. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of giving you Privigen[®] 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.

You may want to read it again.

What Privigen[®] is used for

Your medicine is Privigen[®]. Privigen[®] is a ready-to-use solution for intravenous infusion. Privigen[®] contains human immunoglobulins. Immunoglobulins are also called antibodies and are a type of protein found in the blood. Immunoglobulins are produced by your body's immune system to fight infections caused by bacteria and viruses. If you do not have enough antibodies you

may not be able to fight off diseases.

Your doctor may give you Privigen[®] either for:

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Before you are given Privigen[®]

Make sure you tell your doctor of any reasons you know of why you should not be given this medicine.

Inform your doctor of your blood group, if known.

You must not be given this medicine 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 in Privigen[®] (human immunoglobulins, albumin or proline)
- been told you have antibodies to immunoglobulin A (IgA)

Before you are given this medicine

Tell your doctor if this is your first treatment with this medicine or this type of medicine (a human normal immunoglobulin), or if it has been a long time (several months) since you had your last treatment, or if you have been switched from another human normal immunoglobulin medicine.

Tell your doctor if you have any allergies to any medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- hyperprolinaemia type I or II (a genetic disorder causing high levels of the amino acid proline in the blood)
- diabetes
- 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.
- kidney problems or kidney disease
- high blood pressure
- low blood volume (hypovolaemia)
- a condition that causes low antibody levels in your blood (IgA deficiency, hypogammaglobulinaemia or agammaglobulinaemia with or without IgA deficiency)
- frequent headaches or migraine.

or if you:

- have blood group A, B or AB
- are overweight
- are over 65 years of age

- are taking medicines that can damage your kidneys (nephrotoxic medicines).

Tell your doctor if you are pregnant, plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits of receiving this medicine if you are, or plan to become pregnant or if you are breast-feeding.

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.

Taking other medicines

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

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.

Please tell your vaccinating doctor about your treatment with Privigen® before receiving any vaccination.

Blood tests: Please tell your doctor about your treatment with Privigen® prior to any blood test.

Important information about some of the ingredients in Privigen®

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.

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

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.

How to use Privigen®

Privigen® is usually administered by your doctor or healthcare professional.

Privigen® is intended solely for infusion into a vein. Your doctor will decide how much Privigen® you will need. The amount depends on your illness, your present condition and your body 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.

While you are having Privigen®

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Privigen®.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

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.

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

If you are about to have any blood tests, tell your doctor that

you have been given this medicine. 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.

Side effects

Tell the doctor or nurse as soon as possible if you do not feel well while you are being given Privigen®, even if you do not think how you feel is connected with the medicine.

You may need medical attention if you get side effects.

Along with their intended effects, blood products occasionally cause side effects, some of which are serious. Individuals may react differently to similar doses of the same product. This applies to Privigen®. Side effects are more common with the first dose of Privigen®. Most 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.

Do not be alarmed by the following list of possible common side effects, these are usually mild and short lived. You may not experience any of them. If you have questions, ask your doctor or pharmacist.

Tell your doctor or pharmacist if you have any of these side effects:

- 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
- pain, e.g. infusion site
- skin peeling and redness
- flushing (including hot flush)
- diarrhoea
- weakness/tiredness
- tremor.

If you experience any of the following, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- 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.

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, inability to stand bright light or painful eye movements may occasionally occur after receiving this medicine.

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. Your doctor may conduct blood tests if required.

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. For a full list and explanation of the possible side effects associated with Privigen® please ask your doctor.

If you receive too much (overdose)

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.

After having Privigen®

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:

Storing Privigen®

Keep this medicine where children cannot reach it. Store this medicine in a cool dry place

where the temperature stays below 25°C. Do not freeze. Do not shake the bottles. Protect this medicine from light by keeping the bottles in their cartons.

Disposal

If your doctor stops your treatment or this medicine has passed its expiry date, ask your hospital or pharmacist what to do with any that is left over.

Product description

What it looks like

Privigen[®] is a clear, colourless or pale yellow liquid. It is supplied in glass bottles.

Ingredients

Privigen[®] contains immunoglobulins which are antibodies, a type of protein found in the blood. The concentration of immunoglobulin is 10% or 100 g/L. This medicine contains proline, albumin and water. This medicine does not contain any preservatives.

Distributor

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

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Australian Register Numbers

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

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