

Privigen solution for infusion

Haematology

What is Privigen?

Privigen belongs in a class of medicines called **human normal immunoglobins**. Immunoglobulins are also called antibodies and are blood proteins that help your body to fight infections.

Privigen contains immunoglobulins that have been prepared from the blood of healthy people. It works in exactly the same way as the immunoglobulins that healthy people have naturally in their blood.

Privigen is a clear, or pale yellow liquid.

Why do I need Privigen?

Privigen is used to increase abnormally low immunoglobulin levels in your blood to normal levels. This includes:

- People with a reduced ability or who are unable to produce immunoglobulins. This is called primary immunodeficiencies (PID)
- People with blood cancer (chronic lymphocytic leukaemia), who have low immunoglobulin levels in their blood that mean they keep developing infections that antibiotics can't treat
- People with bone marrow cancer (multiple myeloma), who have low immunoglobulin levels in their blood that mean they keep developing infections that being vaccinated against can't prevent
- People who have low immunoglobulin levels in the blood after receiving a stem cell transplant
- People who have AIDS (Acquired Immunodeficiency Syndrome) and keep getting infections.

Privigen is also used to treat certain inflammatory disorders.

This includes:

- People who don't have enough blood platelets and are at high risk of bleeding or will have surgery in the near future
- People with Guillain-Barré syndrome
- People who have Kawasaki disease
- People who have chronic inflammatory demyelinating polyneuropathy (CIDP).

Do NOT take Privigen if:

- You are allergic to human immunoglobulins or to proline
- You have developed antibodies against immunoglobulins of the type IgA in your blood
- You suffer from hyperprolinaemia type I or II. This is an extremely rare disorder.

Please tell your doctor or nurse if you have any of these.

How will Privigen be given to me?

Privigen is given as an infusion directly into a vein, under the supervision of a doctor or nurse. The infusion will run into your vein from a drip. A nurse will monitor you during the procedure and for 20 minutes afterwards. If you are receiving Privigen at a high infusion rate, for the first time, or after a long break in treatment, you will be closely observed during the whole infusion and for at least an hour afterwards.

A nurse will calculate the correct dose for you, based on your weight, general health, and how well you respond to the treatment. To start with, you will receive Privigen at a slow infusion rate. If you respond well to this, the infusion rate will be gradually increased.

The dose for children and young people is worked out in the same way as the dose for adults.

Will the infusion need to be slowed or stopped?

The infusion will be slowed or stopped if:

- You have an allergic reaction to Privigen. You may be allergic to immunoglobulins without knowing it. They may occur even if you have previously received human immunoglobulins and had tolerated them well. However, true allergic reactions are rare.
- In very rare cases, if you have transfusion-related acute lung injury (TRALI), which can occur after receiving immunoglobulins including Privigen. Symptoms include difficulty in breathing and fever, and typically appear one to six hours after receiving treatment.

Tell your nurse immediately if you notice reactions like these during your Privigen infusion.

Privigen is made from human blood plasma-how safe am I from infection?

Privigen is made from blood plasma (this is the liquid part of the blood). When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on. These include:

- Careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded
- Testing of each donation and pools of plasma for signs of virus or infection
- When processing the blood or plasma, putting measures in place that make viruses inactive or remove them.

Even after these measures, the chance of passing on infections can't be totally excluded. But these steps are considered effective for excluding these viruses:

- HIV
- Hepatitis B
- Hepatitis C
- Non-enveloped Hepatitis A
- Parvovirus B19

Every time you are given a dose of Privigen, the name and batch number of the product are recorded so there is a record of the batches used.

What are the possible side effects of Privigen?

Like all medicines, Privigen can cause side effects, although not everybody gets them. Possible side effects may be reduced or avoided by infusing Privigen at a slow rate.

Main side effects (which may happen to more than 1 in 10 patients) can include:

- Headache
- Upset stomach
- Pain, including back pain, pain in extremities, joints and bones, neck pain, facial pain
- Fever
- Flu-like illness
- Sore throat, blisters in mouth and throat, throat tightness

Very rarely, side effects can include:

- Severe hypersensitive reactions like a fall in blood pressure or anaphylactic shock. You may feel light-headed, dizzy, faint on standing, cold in the hands and feet, have an abnormal heart beat or chest pain, blurred vision.
- Blood clots
- Chest pain and painful breathing
- Temporary non-infectious meningitis. You may have a stiff neck, fever, nausea, headache, sensitivity to light.

Tell your doctor or nurse immediately if you have any of the above symptoms.

What if I am pregnant or breast-feeding?

Tell your doctor or nurse if you are pregnant, plan to become pregnant or are breast-feeding. Your doctor will decide whether you can receive Privigen during your pregnancy or while you are breast-feeding.

Medicines containing antibodies have been used in pregnant and breast-feeding women. Long-term experience has shown that no harm is caused to the pregnancy or the newborn. If you receive Privigen while you are breastfeeding, antibodies in this medicine will also be found in the breast milk, so your baby will also receive these protective antibodies.

Can I drive and use machines?

Some people experience side effects like dizziness or nausea while using Privigen which may affect your ability to drive and use machines. If this happens, you should not drive or use machines until these side effects have stopped.

How does Privigen effect other medicines and blood tests?

Privigen may impair the results of some blood tests for some time after the treatment, so you must tell your doctor you have had Privigen before you have any blood tests.

Privigen may stop some vaccinations from working. This includes vaccinations against measles, mumps, rubella and varicella. Wait for at least three months after your Privigen infusion before having these vaccinations, and tell your doctor you have had Privigen.

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