

You will be asked to provide your express consent (explicit oral or written) to the collection, retention and use of personal information and clinical data to assess authorisation for initial and continuing access to government funded product.

If you don't qualify for government funded product, there are other options available. Please see the National Blood Authority website (www.blood.gov.au) for more information.

Why have I been prescribed this treatment?

There are two major types of conditions where immunoglobulin infusions are used as treatment.

Replacement therapy

Replacement therapy is given to people who do not make enough of their own immunoglobulins (antibodies) to fight infection and maintain a healthy immune system. This can be because of genetic problems from birth (primary) or because of certain diseases or treatments (secondary). Low immunoglobulin levels can occur with certain types of cancers, before or during treatment (such as non-Hodgkin lymphoma and multiple myeloma). People with these cancers need to have immunoglobulin treatment to protect them from infections.

Immunomodulation therapy

Immunomodulation therapy is given to people when their immune system attacks their own body's tissues by mistake. This is called an auto-immune disorder. Immunoglobulin infusions can modulate the immune system to improve some of these conditions. The infusions must be given intravenously.

Examples of auto-immune disorders include:

- ◆ chronic inflammatory demyelinating polyneuropathy (CIDP)
- ◆ Guillain-Barré syndrome
- ◆ inflammatory myopathies
- ◆ auto-immune disorders of the blood.

However, not everyone with these conditions will respond to this treatment and your doctor will need to assess your response to see whether immunoglobulin remains the right treatment for you.

How is it given?

The most common way of giving this treatment is by an infusion through a needle into a vein (IV), but in some cases it can be given as a subcutaneous (SC) infusion, with a needle inserted in to the fat tissue under the skin.

How is the dose determined?

The treatment dose varies with each diagnosis and is also based on body weight. The dose given, the timing between treatments and the number of treatments given depends on your response to treatment and test results. Your doctor will inform you of what is best for you and look at your progress at set times. It is important that your doctor sees you at regular intervals to make sure the treatment is working and to make changes if needed.



What are the risks of infection from a blood product?

All immunoglobulin products have been screened and tested to protect patients from diseases such as hepatitis (B and C) and human immunodeficiency virus (HIV/AIDS). These products have also gone through at least two processes that destroy viruses. There is a risk of infection but it is very low. In Australia, there has never been a reported case of an infection from this treatment.

What are the side effects?

All medical treatment products, including blood products, have risks.

The most common reactions or side effects to immunoglobulin products are:

- ◆ tiredness
- ◆ headache
- ◆ nausea (feeling sick)
- ◆ stomach and back pain

Rarely, more serious allergic reactions occur. Symptoms include:

- ◆ shortness of breath
- ◆ wheezing
- ◆ tongue/throat swelling
- ◆ chest tightness
- ◆ skin rash
- ◆ dizziness
- ◆ low blood pressure

Very rarely there can be an increased risk of blood clotting which in some people may contribute to heart attack, stroke or other vascular problems or worsening renal failure. These almost only occur in people who already have risk factors.

Any of these or any other symptoms should be reported to a doctor or nurse immediately, or before your next treatment.

Are there alternative treatments?

There may be other treatments for your condition. Discuss these with your doctor. Stopping treatment without first talking with your doctor can be dangerous.



When do I need to call the doctor or treatment centre?

Before the infusion

Tell your doctor or nurse of any change in your health or medication, even if it is for a short time or if it is simple such as a minor infection, dehydration or conditions that could cause dehydration including loss of appetite, vomiting or diarrhoea and if you have taken a non-drowsy antihistamine and paracetamol (at home) to prevent some of the side effects.

After the infusion

Sometimes after the infusion and for the next day or two, you might experience flu-like symptoms such as fever, chills, aching joints and muscles. These usually disappear within 24 to 48 hours and are easily treated. Your doctor or nurse can suggest some treatments for you. Sometimes people have reported a severe headache with their eyes being very sensitive to light after an infusion. If this happens please call your doctor or the nurse in your treatment centre.



Regular treatment reviews

All patients on immunoglobulin products must be regularly reviewed by a doctor. Depending on your diagnosis the immunoglobulin treatment may only be required for a limited period. If you are prescribed continuing immunoglobulin treatment, regular consultations with your doctor help measure how the treatment is affecting your health, any dose adjustments to be made, and any side effects to be reported. Your doctor will assess your response to the treatment and may stop your infusions temporarily to reassess your immune system or your response to treatment. Immunoglobulin treatment may not be effective and may no longer be required. Your doctor will advise you of when the reviews should be carried out. Your doctor will also be required to periodically report on your response to treatment for you to continue to access immunoglobulin.

Questions to ask your doctor

Below is a list of questions that you may like to ask your doctor to help you make an informed decision before agreeing to treatment:

- ◆ Why do I need this product?
- ◆ Are there any other treatment options?
- ◆ What are the expected outcomes of this treatment?

Your doctor should discuss any queries you have regarding the treatment and you should be offered written information. You have the right to ask questions and expect those questions to be answered.

Other questions I would like to discuss with my doctor:

Contact details

Hospital: -----
Phone: -----
Doctor: -----
Phone: -----
Treatment centre: -----
Phone: -----

More information

Additional information can be obtained from the following sites:

- ◆ National Blood Authority www.blood.gov.au
- ◆ Australian Red Cross Blood Service www.mytransfusion.com.au
- ◆ National Health and Medical Research Council www.nhmrc.gov.au
- ❖ This brochure was developed with input from relevant consumer groups

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Patient Information: Immunoglobulin Treatment



Your doctor has recommended that, as a part of your treatment, you will be receiving medication called immunoglobulin.

What are immunoglobulins?

These are antibodies made by the body's immune ("defense") system to fight infections and disease. They are normally produced by a type of white blood cell called a B-lymphocyte. All immunoglobulin products are produced from pooled healthy donated blood plasma. All immunoglobulin products used in Australia have been approved by the Therapeutic Goods Administration.

How are immunoglobulin products made available in Australia?

To ensure sustainability of these precious and high cost products, governments have established *the Criteria for the clinical use of intravenous immunoglobulin in Australia 2nd Edition (Criteria)* as the basis for access to government funded products. The product type that you receive (including between Australian and imported products) may change from time to time due to:

- ◆ A clinical decision; and/or
- ◆ National supply contract arrangements.

