

Safety of Immunoglobulins

- Because immunoglobulins are blood products they could **possibly** pass on some infections.
- Immunoglobulin products have a very good history of safety from infection over more than 50 years.
- Important infections such as HIV/AIDS, hepatitis B and hepatitis C have never been spread by immunoglobulins made by CSL Behring from blood donations given by New Zealand donors.
- Blood donations are only collected from donors who are in good health and who do not have any conditions identifiable by standard checks on blood donors, that could be passed on to people receiving immunoglobulins.
- Every blood donation is tested for the infections: HIV/AIDS, syphilis, hepatitis B and hepatitis C. Blood donations are only used if the tests show no evidence of these infections.
- The manufacturing process for making immunoglobulins is able to destroy or remove these and many other viruses.
- There is no evidence that Creutzfeldt Jakob Disease (CJD) or variant CJD has ever been passed on by immunoglobulin products manufactured from human plasma.

Can Immunoglobulins cause adverse effects?

Severe side effects from immunoglobulins are rare.

Mild side effects are common and include:

- Local soreness and stiffness at the site of injection into a muscle. The symptoms are common where a large volume, e.g. 5mL or more, is injected.
- Local soreness and redness is common if the injection is given under the skin.
- An itching rash, feeling of being unwell and fever has been reported occasionally.

True allergic reactions occur rarely. It will be necessary to stop future use of immunoglobulin treatment if this occurs. Allergic reactions may occur in people who lack IgA immunoglobulin. Individual patients may react differently to immunoglobulins and to different batches of these products.

Do Immunoglobulins ever fail to give all of the expected benefits?

- Where an immunoglobulin is used to prevent a viral infection, e.g. hepatitis A or B, measles, chickenpox, etc, the infection may be prevented completely. In some cases only partial protection occurs: the infection may not be prevented but will occur in a milder form. Timing of the injection, and the dose given, may affect the outcome. If given after a viral infection has started, immunoglobulins are not likely to produce much helpful effect.
- Immunoglobulins produce only a short protection effect lasting several weeks or months. The short duration of effect is an expected outcome.
- If the dose of immunoglobulin is too small the desired effect may not be achieved. The dose of treatment is determined from published experience of this treatment.

Your Doctor will be able to discuss these and any related issues with you.

This leaflet provides information to help with informed consent before receiving treatment with immunoglobulins.

If you need more information please ask your Doctor.

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Normal Immunoglobulin, Hepatitis B Immunoglobulin, Tetanus Immunoglobulin, Zoster Immunoglobulin



Your guide
to blood
transfusion

You have been given this leaflet because your Doctor considers you may need treatment with a human immunoglobulin product.

As with any treatment you have the right to decide whether you want to have the treatment or not. You will be asked to sign a Consent Form to show that:

- the benefits, risks and alternatives for your treatment, including transfusion of blood products, have been explained to you,
- you have been able to ask any questions about the treatment, and
- you agree to receive the treatment.

This leaflet answers common questions about immunoglobulin products.

What are Immunoglobulins?

- **Immunoglobulin** is a technical word for **antibodies**. They are natural proteins made by the immune (defence) system of the body.
- Immunoglobulins (antibodies) help the body fight infections.
- The products described in this leaflet are made from blood donations given by unpaid, voluntary New Zealand blood donors. They are manufactured for the New Zealand Blood Service by CSL Behring, Melbourne, Australia.

How do Immunoglobulins fight infection?

- **Viral infections** - They can neutralise viruses and prevent them from starting an infection.
- **Toxins** - They can neutralise bacterial toxins and stop them causing disease, e.g. tetanus.
- **Bacteria** - In large doses immunoglobulins can help fight bacterial infections.

How are Immunoglobulin products given?

They are usually injected into a muscle, such as the buttock or thigh. The amount given depends on the condition treated.

What conditions are treated with immunoglobulins?

Four different immunoglobulin products are described below. They are used to provide immediate protection from some infections. Please read the information about the product(s) relevant to you / your relative.

Normal Immunoglobulin

This product is used to prevent various infections including:

- **Hepatitis A (infectious hepatitis)**

Normal Immunoglobulin can prevent hepatitis A infection. It will give protection for up to 3 - 6 months, depending on the dose. Normal Immunoglobulin may be offered after a person has been exposed to hepatitis A risk in the previous 2 weeks. People who may be offered this treatment are:

- Infants less than 12 months old
- Adults aged over 40 years
- Newborn infants where the mother has developed acute hepatitis A from two weeks before birth to one week after birth.

If Immunoglobulin is not available or is contraindicated, hepatitis A vaccine may be offered as an alternative.

Immunoglobulin is not normally offered if more than 2 weeks have elapsed since exposure occurred.

Normal Immunoglobulin may also be used to protect a person who has depressed immune function and has a recent or ongoing risk for hepatitis A.

Vaccines against hepatitis A are available and are preferred for other individuals who have normal immune function. Vaccines will provide long lasting immunity against hepatitis A, whereas Normal Immunoglobulin will protect for only a few months.

Vaccination is preferred where an occupational or environmental risk for hepatitis A will be ongoing.

- **Other viral infections**

Normal immunoglobulin may be offered to a person who is not immune and has been exposed to any of: measles (morbilli), poliomyelitis and occasionally other infections.

Hepatitis B Immunoglobulin

Protects against hepatitis B infection. It is offered as protection for:

- An infant born to a woman who has chronic hepatitis B infection or has acute hepatitis B in the last three months of pregnancy. **Note:** The infant should also receive hepatitis B vaccine at the same time to provide long term immunity to hepatitis B.
- A person who has not been immune to hepatitis B infection and has been exposed to a risk of this infection from blood or body fluids.

Tetanus Immunoglobulin

Protects against tetanus. It is offered to a person who has a tetanus-prone wound if any of the following apply:

- Has not been immunised against tetanus.
- Immunised more than ten years ago.
- Immunisation history is not certain.

Note: A person offered Tetanus immunoglobulin should also be offered Tetanus Vaccine to provide long term immunity to this infection.

Zoster Immunoglobulin

Used to protect a person who is not immune to chickenpox, has been exposed to this infection, and has a risk of severe illness from this infection.

It is usually offered after exposure to chickenpox to:

- Children who have been immunosuppressed, e.g. receiving chemotherapy for leukaemia or cancer, a severe autoimmune disorder or an organ transplant.
- Congenital or acquired immune deficiency.
- A newborn infant who is exposed to chickenpox from any source, including maternal chickenpox that has occurred within 7 days before birth and 7 days after birth.
- Premature infants exposed to risk of chickenpox if the mother is not immune to this infection, or the infant is born before 28 weeks of pregnancy.

Zoster immunoglobulin should normally be injected within 96 hours of exposure to chickenpox but may be given up to 10 days after exposure.

Note: Alternative commercial immunoglobulin products may be supplied if local products are not available.