

Normal Immunoglobulin-VF

Human Normal Immunoglobulin, solution for intramuscular injection.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Normal Immunoglobulin-VF. It does not contain complete information about Normal Immunoglobulin-VF. It does not take the place of talking to your doctor.

If you have any concerns about using this medicine, ask your doctor. Follow your doctor's advice even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference.

The information in this leaflet is subject to change. Please check with your doctor whether there is any new information about this medicine that you should know since you were last treated.

What Normal Immunoglobulin-VF is used for

Normal Immunoglobulin-VF is prepared from blood obtained from voluntary donors. Normal Immunoglobulin-VF contains

protein substances called antibodies which can provide protection against some infectious diseases. It can prevent infection if given to people with low levels of antibodies.

Normal Immunoglobulin-VF is used to treat conditions where low antibody levels in the blood are inherited, and in other diseases where a lack of antibody may cause frequent infections.

It is also used to prevent infection by viruses such as poliomyelitis, hepatitis A, and measles in those coming in contact with a source of infection, such as family members.

Ask your doctor if you have any questions about why Normal Immunoglobulin-VF has been prescribed for you. Your doctor will have assessed the risks and benefits associated with the use of this medicine for you.

Before you are given Normal Immunoglobulin-VF

Normal Immunoglobulin-VF must not be used if you have a

history of allergy to this medicine. Tell your doctor if you have allergies to any other medicines, or if you have ever had an allergic reaction to an injection.

Tell your doctor also if you:

- have previously been advised that you have immunoglobulin A (IgA) deficiency
- are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores.
- have had any vaccination during the last two weeks
- 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 any other medical conditions.

Pregnant or lactating women should discuss use of Normal Immunoglobulin-VF with their doctor.

About blood products

This product is made from human plasma obtained from voluntary donors. When products are made from human blood and injected into you, it is possible that viruses or other substances could be present in the product and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or human parvovirus B19 and theoretically the Creutzfeldt-Jakob Disease (CJD) agent. There could also be other infectious agents some of which may not as yet have been discovered.

To reduce the risk of this happening, extra steps are taken when manufacturing this product. Strict controls are applied to the selection of blood donors and donations. The product is specially treated to remove and kill certain viruses. These special treatments are considered effective against viruses known as enveloped viruses such as HIV, hepatitis B virus and hepatitis C virus, and the non-enveloped viruses, such as hepatitis A virus and human parvovirus B19. Additionally, the product contains specific antibodies which can provide some protection against human

parvovirus B19. Despite these measures, the risk of viral and other agent's infectivity cannot be totally eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

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

How to use Normal Immunoglobulin-VF

Your doctor will determine the dose(s) of Normal Immunoglobulin-VF that you are to receive. Your doctor will give you the injection. It will be injected into the muscle. If a large volume of product is required, you may receive more than one injection.

Side effects

Along with their intended effects, medicines may cause some unwanted effects, which can sometimes be serious. Furthermore, individual patients may react differently to the same dose of the same medicine. This applies to Normal Immunoglobulin-VF.

Reactions are very uncommon after injection with Normal Immunoglobulin-VF. However, some pain, redness and stiffness may be apparent at the injection

site. This may occur after any large injection into a muscle.

Occasionally mild fever, chills, drowsiness or discomfort may be felt and an itchy rash may develop.

If any of these effects are severe, or if you are worried about any other symptoms after the injection, consult your doctor.

Contact your doctor immediately if you experience signs and symptoms such as shortness of breath, chest pain, pain and swelling of a limb, weakness or numbness on one side of the body after receiving Normal Immunoglobulin-VF.

Normal Immunoglobulin-VF can interfere with some live vaccines (e.g. measles and polio), even up to three months later. Advise your doctor if you are to receive other vaccines within three months of receiving Normal Immunoglobulin-VF.

Overdose

The consequences of overdosage are not known.

Storing Normal Immunoglobulin-VF

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Do not use after the expiry date shown on the label.

Further information

Normal Immunoglobulin-VF can only be obtained on a doctor's prescription. This leaflet does not contain the complete information about Normal Immunoglobulin-VF. If you require further information about Normal Immunoglobulin-VF and your treatment generally, or if you have any questions or are not sure about something in this leaflet, consult your doctor.

Product description

What it looks like

Normal Immunoglobulin-VF is a clear, colourless, viscous (thick) solution. It is available in glass bottles.

Ingredients

Each bottle of Normal Immunoglobulin-VF is a sterile solution containing 160 mg/mL blood proteins of which at least 98% is immunoglobulins. It also contains 22.5 mg/mL glycine.

Manufacturer

Normal Immunoglobulin-VF is manufactured in Australia by:

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

Distributor

Australian Red Cross Blood Service

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Australian Register Numbers

2 mL: AUST R 61215

5 mL: AUST R 61216