Rh(D) Immunoglobulin-VF

Human Anti-D Rh_o Immunoglobulin, solution for intramuscular injection.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rh(D) Immunoglobulin-VF. It does not contain complete information about Rh(D) 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 Rh(D) Immunoglobulin-VF is used for

Rh(D) Immunoglobulin-VF is manufactured from human plasma (the liquid component of blood) collected by Australian Red Cross Lifeblood. Rh(D) Immunoglobulin-VF contains protein substances called antibodies which are an important component of the body's natural defence system.

If a pregnant woman has an Rh(D) negative blood group and her baby is Rh(D) positive, the baby's blood is incompatible with the mother's and this could cause Haemolytic Disease of the Newborn (HDN). HDN may lead to serious complications such as severe anaemia, brain damage and even death of the baby in rare cases. The antibodies in Rh(D) Immunoglobulin-VF can prevent HDN from developing.

Rh(D) Immunoglobulin-VF is also given to a woman who has an Rh(D) negative blood group after she has given birth to an Rh(D) positive baby to prevent HDN from occurring during the next pregnancy. Sometimes it is given on other occasions when a woman of child-bearing age may become exposed to Rh(D) positive blood: for example, after blood transfusion, amniocentesis (taking a sample of the fluid surrounding the unborn baby), miscarriage or stillbirth.

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

Before you are given Rh(D) Immunoglobulin-VF

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

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 Rh(D) Immunoglobulin-VF (human immunoglobulins or glycine)
- been told you have antibodies to immunoglobulin A (IgA).

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 a blood type Rh(D)-positive
- have a blood type Rh(D)-negative but have been previously exposed to Rh(D)-positive blood
- 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.
- suffer from a blood disorder or blood clotting problem
- have had any vaccination during the last two weeks or intend to receive one in the next three months
- have any other medical conditions.

Vaccinations: Please inform your doctor if you are planning to have a vaccination. Rh(D) Immunoglobulin-VF may impair the effect of some virus vaccines such as measles, mumps, rubella and chicken pox 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. Therefore, your vaccinating doctor should check the effectiveness of the measles vaccination.

Pregnant or lactating women should discuss use of Rh(D) Immunoglobulin-VF with their doctor.

About blood products

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 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 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 Rh(D) Immunoglobulin-VF

Your doctor will determine the dose(s) of Rh(D) 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.

If your body mass index (BMI) is greater than or equal to 30 (calculated by dividing your body weight by the square of your height), the injection of Rh(D) Immunoglobulin-VF may not be fully effective. Therefore, you should consult with your doctor.

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 Rh(D) Immunoglobulin-VF.

Reactions are very uncommon after injection with Rh(D) 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.

Overdose

The consequences of overdosage are not known.

Storing Rh(D) 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

Rh(D) Immunoglobulin-VF can only be obtained on a doctor's prescription. This leaflet does not contain the complete information about Rh(D) Immunoglobulin-VF. If you require further information about Rh(D) 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

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

Ingredients

Each bottle of Rh(D) Immunoglobulin-VF is a sterile solution containing an Rh(D) antibody content of 250 IU per bottle/≥10 mg/mL blood proteins or an Rh(D) antibody content of 625 IU per bottle/≥10 mg/mL blood proteins of which at least 98% is immunoglobulins. It also contains 22.5 mg/mL glycine.

Manufacturer

Rh(D) 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 Lifeblood

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250 IU: AUST R 76643

625 IU: AUST R 61217