

## WinRho SDF™

Anti-D (Rho) Immunoglobulin (Human) for Injection

### Consumer Medicine Information

#### What is in this leaflet?

This leaflet answers some common questions about WinRho SDF™. It does not contain complete information about WinRho SDF™. 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. However, 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 with this medicine.

#### What Win Rho SDF™ is used for

WinRho SDF™ 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 Rhesus disease in the baby, a condition which results in reduced red blood cells and iron stores. The antibodies in WinRho SDF™ can prevent Rhesus disease from developing in the baby.

WinRho SDF™ is also given to a woman who has an Rh(D)-negative blood group after she has given birth to a Rh(D)-positive baby to prevent Rhesus disease 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 WinRho SDF™ has been prescribed for you. Your doctor will have assessed the risks and benefits associated with the use of this product for you.**

#### Before your doctor gives you WinRho SDF™

##### SPECIAL WARNING

This medicine is made from human plasma. When medicines are made from human plasma and injected into you, it is possible that viruses or other substances could be present in the medicine and cause an illness. These could be viruses such as hepatitis, HIV (human immunodeficiency virus), or parvovirus B19 and theoretically the Creutzfeldt-Jacob 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 medicine. Strict controls are applied when selecting blood donors and donations. The medicine is specially treated to remove and kill certain viruses. This special treatment is considered effective against viruses known as enveloped viruses such as HIV, and hepatitis B and C viruses, and the non-enveloped viruses, hepatitis A and 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 medicine with your doctor.**

**WinRho SDF™ must not be used if you have a history of allergy to this product. 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-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
- are pregnant or breast-feeding
- become pregnant during your treatment
- have had any vaccination during the last two weeks
- have any other medical conditions

#### How to use WinRho SDF™

Your doctor will determine the dose(s) of WinRho SDF™ that you are to receive. Your doctor will give you WinRho SDF™ as an infusion, that is, an injection given slowly into the vein or it will be injected into the muscle.

If a large volume of product is required, you may receive more than one injection.

**If you want further information, consult your doctor.**

#### Unwanted 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 WinRho SDF™.

Reactions to WinRho SDF™ are rare in Rh(D)-negative individuals. Discomfort and slight swelling at the site of the injection, fever, skin rashes, nausea, vomiting and aching muscles and joints have been reported in a small number of cases. Headache, chills, sweating, low blood pressure, dizziness and abdominal pain or back pain have also been reported.

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

WinRho SDF™ may 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 WinRho SDF™ or have just received a vaccine in the last two weeks.

**Contact your doctor immediately if you experience any of these symptoms at any time: fever, loss of appetite, extreme tiredness, abdominal pain.**

**If you want further information, or if you are worried about any other symptoms after the infusion, consult your doctor.**

#### Overdose

The consequences of overdosage are not known. However, administering a larger than recommended dose should not be harmful.

There are no reports of known overdoses in patients being treated for Rh(D) disease.

#### How to store WinRho SDF™

**Store at 2°C to 8°C (Refrigerate. Do not freeze).**

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

#### Further information

WinRho SDF™ can only be obtained on a doctor's prescription. This leaflet does not contain the complete information about WinRho SDF™. If you require further information about WinRho SDF™ 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

WinRho SDF™ is a white to off-white powder contained in a single dose glass vial. The product is supplied with one single dose vial of 0.9% Sodium Chloride for reconstitution.

##### Ingredients

Each vial of WinRho SDF™ is a sterile freeze dried gamma globulin (IgG) fraction of human plasma containing antibodies to Rho(D). It also contains glycine, sodium chloride and polysorbate 80.

##### Manufacturer

WinRho SDF™ is manufactured by:  
Cangene Corporation  
Winnipeg, Canada R3T 5Y3

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