

PART III: CONSUMER INFORMATION

WinRho® SDF

Rh₀ (D) Immune Globulin (Human) for injection

This leaflet is part III of a three-part "Product Monograph" published when WinRho® SDF was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about WinRho® SDF. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- Protection (prophylaxis) against the development of harmful antibodies in Rh-negative women exposed to Rh-positive blood. This exposure can occur in an Rh-negative woman:
 - o Upon receipt of an Rh-positive blood transfusion
 - o During pregnancy or after delivery if the baby is Rh-positive or the Rh status is unknown.
- Treatment of Immune Thrombocytopenic Purpura (ITP)
 - o In children with chronic or acute ITP
 - o In adults with chronic ITP
 - o In children and adults with ITP secondary to HIV infection

What it does:

Protection (prophylaxis) against the development of harmful antibodies in Rh-negative women exposed to Rh-positive blood.

Pregnant women often have different blood groups from their babies. This is normal and usually not a problem. However, in some cases, these blood groups differ in an important way, which is the presence or absence of a particular protein on the outside of the red blood cell. If you have this protein, you are "Rh positive". If you do not have this protein, you are "Rh negative".

Sometimes during pregnancy and delivery, a small amount of the baby's blood can cross the placenta and enter the mother's blood stream. This can also happen in events such as a miscarriage, abortion and amniocentesis. If this transfer of blood occurs from an Rh positive fetus to an Rh negative mother, the mother's immune system will see the baby's blood as "foreign" and will produce antibodies which destroy the baby's blood cells. In the first pregnancy, most of these antibodies will remain in the mother's circulation and the baby is usually not significantly affected. During subsequent pregnancies, however, a problem may occur if the new baby is Rh positive and if there is another transfer of blood across the placenta. The mother's immune system has a good memory. It can rapidly produce the same antibodies again, and they can re-cross the placenta in large numbers and start to destroy the new baby's own blood before birth, causing a number of serious complications.

WinRho® SDF is an injection of antibodies administered with every pregnancy, when the mother is known to be Rh-negative. It works in your bloodstream to destroy any circulating blood cells from your baby before your immune system has a chance to make its own antibodies. Your baby is not affected by this injection.

Injections may also be given in connection with abortion, miscarriage or amniocentesis. As a result of the WinRho® SDF injection, your immune system never makes its own antibodies to your baby's Rh positive red blood cells, so you and your baby are protected.

Treatment of ITP

ITP is a bleeding disorder caused by an abnormally low level of platelets. Platelets are found in the bloodstream and are needed for blood to clot properly. When blood does not clot properly, there is a tendency to bruise and bleed easily. ITP is a disorder of the immune system. Usually, the body will manufacture antibodies which coat disease-causing organisms, aiding their removal by the spleen. This process helps the immune system fight infection in the body. In ITP, the body mistakenly produces antibodies against its own platelets. When these antibodies coat the platelets, it results in their rapid and premature destruction by the spleen. ITP can affect adults or children; it can occur without warning and for no apparent reason, or it can occur as a result of a primary illness or infection. There is no evidence to suggest that ITP is inherited or related to personal habits or diet. It cannot be passed to other people like the common cold.

WinRho® SDF contains a concentration of antibodies which specifically bind to Rh positive red blood cells. When administered to an Rh positive patient, it is thought that WinRho® SDF coats the Rh positive red cells, causing their destruction by the spleen, thereby preventing the destruction of platelets. This results in increased levels of circulating platelets and an alleviation of the symptoms of ITP.

When it should not be used:

- WinRho® SDF must not be used if you are hypersensitive (allergic) to human immunoglobulin or to any other ingredients of WinRho® SDF.
- WinRho® SDF should not be used for Rh prevention if you are Rh-positive or if you are Rh-negative but have been previously Rh immunized.
- WinRho® SDF should not be used to treat ITP if you are Rh-negative, or if you are Rh-positive and have had your spleen surgically removed.
- WinRho® SDF should not be used to treat ITP if you have Leukemia, lymphoma or active viral infections such as Hepatitis C or Epstein Barr Virus (EBV).
- WinRho® SDF should not be used to treat ITP if you have a condition that causes red blood cell destruction (i.e. haemolytic anemia).
- WinRho® SDF should not be used to treat patients who are IgA deficient.

What the medicinal ingredient is:

Rh₀ (D) Immune Globulin (Human)

What the important nonmedicinal ingredients are:

- Lyophilized (Freeze-dried) Formulation*
- Human plasma protein*
- Sodium Chloride*
- Glycine*

Polysorbate 80

Liquid Formulation

Human plasma protein

Maltose

Polysorbate 80

WinRho[®] SDF may contain trace amounts of tri-n-butyl phosphate and Triton X-100

What dosage forms it comes in:

Lyophilized: 600 IU (120 µg), 1500 IU (300 µg),
5000 IU (1000 µg)

Liquid: 600 IU (120 µg), 1500 IU (300 µg),
2500 IU (500 µg), 5000 IU (1000 µg),
15 000 IU (3000 µg)

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- WinRho[®] SDF is made from human plasma, which may contain the causative agents of viral disease. The risk of getting a disease from this product has been reduced by screening plasma donors, testing for the presence of certain viruses and by utilizing manufacturing steps that inactivate and remove certain viruses. However, there is still a possibility that plasma products could transmit disease
- In rare cases WinRho[®] SDF may cause intravascular hemolysis or its complications. Before using WinRho[®] SDF, discuss the risks and the benefits with your doctor.
- The liquid formulation of WinRho[®] SDF contains maltose. Maltose in similar products has been shown to give falsely high blood glucose levels in certain types of blood glucose testing systems.
- Allergic or anaphylactic reactions are rare. These reactions can occur in patients with a history of allergies to blood products or in patients lacking the IgA blood protein.

BEFORE you use WinRho[®] SDF talk to your doctor or pharmacist if:

- You have experienced allergic reactions to blood products in the past
- You have a known IgA deficiency
- You have recently received any vaccinations
- You are allergic to WinRho[®] SDF or any of its ingredients or components of the container
- You are taking any other medications including over the counter medications and herbal products.
- You are > 65 years of age and have other co-existing medical conditions such as those related to your heart, lungs, liver or kidneys.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with WinRho[®] SDF have not been established.

Immune globulins like WinRho[®] SDF may impair the effectiveness of certain live virus vaccines such as measles, rubella (i.e. German measles), mumps and varicella (i.e. chickenpox). Talk to your doctor if you have been recently vaccinated.

PROPER USE OF THIS MEDICATION

Usual dose:

Protection against the development of harmful antibodies in Rh-negative women exposed to Rh-positive blood

Pregnancy and other obstetric conditions:

A dose of 1,500 IU (300 µg) of WinRho[®] SDF is given at 28 weeks of pregnancy. A 600 IU (120 µg) dose of WinRho[®] SDF is given after delivery of an Rh-positive baby.

A 600 IU (120 µg) dose of WinRho[®] SDF is given after therapeutic abortion, amniocentesis (after 34 weeks of pregnancy), or other manipulation late in pregnancy (after 34 weeks of pregnancy).

A dose of 1,500 IU (300 µg) of WinRho[®] SDF is given after amniocentesis before 34 weeks of pregnancy or after chorion villus sampling, and should be repeated every 12 weeks while you are pregnant. In case of threatened abortion, WinRho[®] SDF is given as soon as possible.

Transfusion

If you are exposed to Rh-positive blood, WinRho[®] SDF is given at 45 IU (9 µg)/mL of blood. If you are exposed to Rh-positive red blood cells, WinRho[®] SDF is given at 90 IU (18 µg)/mL of cells.

Treatment of ITP

WinRho[®] SDF is given at an initial dose of 250 IU/kg (50 µg/kg). If you need additional therapy to increase your platelet counts, then a dose of 125 to 300 IU/kg (25 to 60 µg/kg) is given.

Overdose:

In the treatment of ITP patients, WinRho[®] SDF overdoses have been reported to result in more chills, fever and headaches in patients as well as greater decreases in red blood cell measures (i.e. hemolysis with urine discoloration). One of these cases resulted in death. Patients should discuss with their physician the WinRho[®] SDF dose they are receiving and report the side effects to the physician without delay.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

GENERAL

If you have been told that you have an IgA deficiency, you have a greater risk of having an allergic reaction to WinRho[®] SDF. While there is only a rare chance that you may experience a sudden, severe allergic reaction after receiving WinRho[®] SDF, you should be aware of the symptoms of an allergic reaction. These are:

- hives,
- rash,
- chest tightness,

- wheezing,
- shortness of breath,
- feeling light-headed or dizzy when you stand (this could mean a drop in blood pressure).

If you experience any of these symptoms, **call your doctor immediately.**

Protection against the development of harmful antibodies in Rh-negative women exposed to Rh-positive blood

Reactions to WinRho[®] SDF are rare in Rh-negative individuals. Discomfort or slight swelling at the injection site and slight elevation in temperature have been reported in a small number of cases.

Treatment of ITP

Most WinRho[®] SDF patients do not experience any drug related adverse effects. Among the few who do, the most commonly reported effects include headache, chills and fever. Rare side effects such as vomiting, nausea, low blood pressure, an increase in your heart beat, joint pain, anemia (decrease in red blood cells), intravascular hemolysis (destruction of red blood cells), back pain, shaking chills, hemoglobinuria (brownish discoloration of urine), and acute renal insufficiency (kidney failure) may also occur. If you experience any of the following symptoms after receiving WinRho[®] SDF, you should **call your doctor immediately:**

- back pain,
- discolored or darkened urine,
- decreased urine production,
- jaundice
- swelling,
- shortness of breath.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Discomfort or swelling at injection site, elevation in temperature	✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Uncommon	Allergic reaction		✓	✓
	Back pain, discoloured urine, darkened urine, decreased urine output, jaundice, swelling, shortness of breath		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking WinRho[®] SDF, contact your doctor or pharmacist.

HOW TO STORE IT

Store WinRho[®] SDF under refrigeration.

Do not freeze.

Do not use after expiration date.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax: 866-678-6789

By email: cadmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.cangene.com/>

or by contacting Cangene Corporation's Pharmacovigilance Department at 1-800-768-2304 (phone) or 1-800-768-2281 (fax).

This leaflet was prepared by Cangene Corporation

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