

Understanding Your Therapy for ITP*



WinRho[®] SDF

Rh₀(D) Immune Globulin (Human)

*Immune Thrombocytopenic Purpura

CANGENE

ITP Can Be Treated

Your physician is familiar with the treatments available and will select the one that is best for you.

Anti-D WinRho® SDF is an anti-D immunoglobulin that is specially prepared to have high levels of the specific antibody, anti-D. WinRho® SDF is believed to work by blocking the destruction of platelets in the spleen. WinRho® SDF is effective in increasing platelet counts in chronic and



acute pediatrics and in chronic adults who are Rh positive.

WinRho® SDF is given intravenously and administered in about five minutes. One of the benefits of WinRho® SDF is that it only takes one day to administer.

IVIG IVIG (intravenous immune globulin) is a mixture of antibodies that works by blocking the destruction of platelets in the spleen.

A large volume of IVIG is given intravenously and administration can take several hours over a period of 1-5 days.

Oral Steroids Steroids are a common initial therapy; however, the beneficial effects of steroids generally do not last for an extended period of time. Steroids are thought to work by slowing the destruction of platelets in the spleen. Steroids may suppress the immune system, which increases the risk of an infection. Oral steroids are usually taken daily for a period of 21 days.

Splenectomy A splenectomy is the surgical removal of the spleen. It is usually recommended only if other treatments have not successfully raised platelet counts. Although removing the spleen may treat the disease in some patients, there is an increased risk of infections.

What is ITP?

Immune Thrombocytopenic Purpura (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.



What Causes ITP?

The actual cause of ITP is unknown. It 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. It can be acute, lasting less than six months or it can be chronic, lasting longer than six months. In some cases, ITP resolves without treatment; however, in many cases, treatment is required.

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.



How Does WinRho® SDF Work in the Treatment of ITP?

WinRho® SDF contains a concentration of anti-bodies which specifically bind to Rh-positive red blood cells. *Rh* refers to a particular protein on the outside of the red blood cell. If your red blood cells have this protein, your blood type is *Rh-positive*; if they don't, your blood type is *Rh negative*. About 85% of the population in North America is Rh positive.

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.

In clinical trials, WinRho® SDF has been demonstrated to be highly effective, with a response rate of greater than 75% in all patient categories for which it is indicated.

WinRho® SDF Administration

WinRho® SDF can be administered in about five minutes. Your caregiver will prepare a single injection, which will be injected into a suitable vein. Depending on your body's response to the treatment, you may require subsequent injections at intervals to be determined by your doctor.



Adverse Effects of WinRho® SDF Therapy

Many WinRho® SDF patients do not experience any drug related adverse effects. Among the few patients who do, the most commonly reported effects include headache, chills and fever. Other reactions include back pain, shaking chills and pink urine.

WinRho® SDF ITP Response Rates

TOTAL PATIENTS

OVERALL RESPONSE RATE

Childhood Chronic ITP: 24 ^A Patients	79%
Childhood Acute ITP: 38 ^B Patients	84%
Adult Chronic ITP: 24 ^C Patients	88%
ITP Secondary to HIV Infection: 63 ^C Patients	90%

A Response defined as a platelet increase to at least $\geq 50,000/\text{mm}^3$ and a doubling of the baseline platelet count.

B Response defined as an increase in platelet count of $\geq 50,000/\text{mm}^3$

C Response defined as an increase in platelet count of $\geq 20,000/\text{mm}^3$

WinRho® SDF Safety

WinRho® SDF is made from the antibodies of carefully selected donors. Strict precautions are taken to screen and test these donors and their blood for any potentially infectious agents. Any donor or plasma donation that does not fully meet current safety standards is rejected.

In addition to stringent donor selection and collection criteria, special manufacturing processes are used to remove viruses such as HIV, hepatitis A, hepatitis B, hepatitis C, and B-19 parvovirus.

Although the potential to transmit viruses through blood products cannot be totally eliminated, the many precautions taken in the manufacture of WinRho® SDF ensure that such risks are dramatically reduced.



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For more information please refer to the product monograph at www.cangene.com. For inquiries, please call us toll-free in Canada at 1 877 CANGENE (226 4363).

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