For use in the treatment of ITP, do not use WinRho SDF in:

- patients with known anaphylactic or severe hypersensitivity responses to human immune globulin products
- patients with autoimmune hemolytic anemia
- patients with pre-existing hemolysis or in patients at high risk for hemolysis
- patients who are IgA deficient with antibodies against IgA

The liquid formulation of WinRho SDF contains maltose. Maltose in IGIV products has been shown to give falsely high blood glucose levels in certain types of blood glucose testing systems. Due to the potential for falsely elevated glucose readings, only testing systems that are glucose-specific should be used to test or monitor blood glucose levels in patients receiving WinRho SDF Liquid.

WinRho SDF is made from human plasma. It may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Use of Immune Globulin Intravenous (IGIV) products, particularly those containing sucrose, have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephropathy, and death. WinRho SDF does not contain sucrose. For patients at risk of renal dysfunction or failure, administer WinRho® SDF at the minimum infusion rate practicable.

In Rho(D)-positive patients with ITP, side effects related to the destruction of Rho(D)-positive red blood cells, most notably a decrease in hemoglobin, can be expected. In most cases, the reduction in hemoglobin is slow and predictable and if it occurs, it does not require specific treatment. Anemia may also occur in patients with ITP treated with splenectomy, and in some, it may be severe even after splenectomy. The degree of anemia may be related to the size of the spleen, and patients with an enlarged spleen may require splenectomy.

Thrombotic events may occur following treatment with WinRho SDF and other IGIV products. Noncardiogenic pulmonary edema [transfusion-related acute lung injury (TRALI)] may occur in patients following IGIV treatment.

General adverse reactions associated with the use of WinRho SDF include body weakness, abdominal or back pain, low blood pressure, paleness, diarrhea, abnormal blood work, joint pain, muscle pain, dizziness, abnormal movement, sleepiness, itchiness, rash, and sweating. In the treatment of ITP, the most common adverse events (≤ 2% of infusions) were headache, chills, and fever.

Please see accompanying WinRho SDF Prescribing Information for full prescribing details.
WARNING: INTRAVASCULAR HEMOLYSIS (IVH)

Intravascular hemolysis (IVH) leading to death has been reported in patients treated for immune thrombocytopenic purpura (ITP) with WinRho® SDF [Rho(D) Immune Globulin Intravenous (Human)].

IVH can lead to clinically compromising anemia and multi-system organ failure including acute respiratory distress syndrome (ARDS).

Serious complications including severe anemia, acute renal insufficiency, renal failure and disseminated intravascular coagulation (DIC) have also been reported.

Closely monitor patients treated with WinRho SDF for ITP in a healthcare setting for at least eight hours after administration. Perform a dipstick urinalysis at baseline, 2 hours, 4 hours after administration, and prior to the end of the monitoring period. Alert patients and monitor the signs and symptoms of IVH including back pain, shaking chills, fever, and discolored urine or hematuria. Absence of these signs and/or symptoms of IVH within eight hours do not indicate IVH cannot occur subsequently. If signs and/or symptoms of IVH are present or suspected after WinRho administration, post-treatment laboratory tests should be performed including plasma hemoglobin, haptoglobin, LDH, and plasma bilirubin (direct and indirect).

Please see pages 14-15 for Important Risk Information.

Please see accompanying WinRho SDF Prescribing Information for full prescribing details.
This booklet explains some of the causes, symptoms and management of immune thrombocytopenic purpura (ITP), including treatment with WinRho® SDF [Rh₀(D) Immune Globulin Intravenous (Human)]. This information is intended to supplement, not replace, a discussion with your health care provider.

For definitions of medical terms that appear in orange type, please check the glossary on page 13.
Introduction to ITP

ITP is a bleeding disorder. It occurs because of a reduction in cells that cause the blood to clot. This can cause abnormal bleeding and bruising. Sometimes ITP occurs after an infection, particularly in children. Other times, there is no obvious trigger.

Occurrence of ITP

ITP occurs in more than 30,000 people in the United States each year; about half are children.¹

Symptoms of ITP

The symptoms of ITP are related to bleeding under the skin or in mucous membranes. Bleeding symptoms may not always occur. When they do, they can include²:

- Bruising on the skin or gums
- Bleeding from the mouth, gums, or gastrointestinal (GI) tract
- Red dots on the skin
- Nose bleeds
- Blood in the urine
- Heavy periods

Types of ITP

ITP can go away within a few months or it can last for a year or longer. ITP is divided into 3 categories: newly diagnosed (lasting less than 3 months), persistent (lasting 3 to 12 months), and chronic (lasting longer than 12 months).³

Newly diagnosed ITP is sometimes called acute ITP, which is the most common type among children.¹

Chronic ITP is more common in adults. Women are approximately 2 times more likely to get ITP as men.¹

ITP that develops for no apparent reason is called primary ITP. When ITP occurs in someone who has another medical condition, such as infection with the hepatitis C virus, it is called secondary ITP.³

Please see pages 14-15 for Important Risk Information and Boxed Warning.

Please see accompanying WinRho® SDF [Rh(D) Immune Globulin Intravenous (Human)] Prescribing Information for full prescribing details.
Causes of ITP

ITP is an autoimmune disorder. It involves the immune system, which normally protects against foreign invaders like viruses or bacteria. In ITP and other autoimmune disorders, the immune system mistakes some of the body’s own cells for foreign substances.¹

In the case of ITP, immune cells mistakenly attack blood cells called platelets. Platelets are designed to stick together when there is a small wound in a blood vessel, sealing it shut.

This mistaken attack causes the number of platelets in the blood to drop, which can lead to abnormal bleeding or bruising. Normally, a person has 100,000 to 400,000 platelets in each microliter of blood. People with ITP have fewer than 100,000. Up to half of adult ITP patients may have platelet counts of less than 10,000.⁴
Treatment

**First-line treatment of ITP**

There are 3 types of treatments that are generally used to treat ITP when it first develops. These are called *first-line treatments*:\(^3\)

**Corticosteroids:** These are often the first treatment given for ITP. Although corticosteroids, such as prednisone, are effective they are only given for a short time due to the risk of side effects. Typical side effects include: facial swelling, upset stomach, abdominal pain, irritability, mood swings, high blood pressure, and difficulty sleeping. More serious side effects can occur with prolonged use.\(^3\)

**Anti-D immune globulin:** This treatment is made from the plasma of blood donors. It contains a specific type of antibody. This antibody is believed to help prevent the destruction of platelets in the spleen.\(^3\)

Anti-D immune globulin can be infused intravenously over a period of a few minutes. Side effects are similar to those seen with IVIG.\(^3\)

**Intravenous immune globulin (IVIG):** IVIG is made from the plasma of a larger number of donors. IVIG contains many different types of antibodies. Some of these antibodies are thought to help block the destruction of platelets in the spleen.\(^3\)

IVIG is given intravenously. Each infusion takes several hours and may be repeated for several days. Common side effects of IVIG include headaches, fever, and chills.\(^3\)

**Second-line treatments for ITP**

Second-line treatments are sometimes given after the doctor has tried first-line treatments.

**Thrombopoietin-receptor agonist (TPOs):** These agents work in a different way to raise platelet levels. Instead of acting on the immune system to prevent platelet destruction, TPOs stimulate the body to produce more platelets.\(^3\)
TPOs are generally used to keep platelet levels elevated after the first-line treatments described above have failed. TPO’s are licensed for adult ITP patients.

**Splenectomy:** If drug treatment fails, the spleen is sometimes surgically removed. As with any surgical procedure, there are risks involved. Splenectomy can make a person more susceptible to infections.1,3

Please see pages 14-15 for Important Risk Information and Boxed Warning.

Please see accompanying WinRho SDF Prescribing Information for full prescribing details.
Treatment with **WinRho® SDF**

[Rh\textsubscript{0}(D) Immune Globulin Intravenous (Human)]

WinRho SDF, an anti-D immune globulin, has been used to treat ITP for more than 15 years.

WinRho SDF [Rh\textsubscript{0}(D) Immune Globulin Intravenous (Human)] must be administered via the intravenous route when used in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomized, Rh\textsubscript{0}(D)-positive:

- children with chronic or acute ITP,
- adults with chronic ITP, or
- children and adults with ITP secondary to HIV infection

The safety and efficacy of WinRho SDF has not been evaluated in clinical trials for patients with non-ITP causes of thrombocytopenia or in previously splenectomized patients or in patients who are Rh\textsubscript{0}(D)-negative.
How WinRho SDF works*

The antibodies in WinRho SDF coat red blood cells in your body.

These antibody-coated red blood cells protect platelets by acting as decoys for the macrophages. Instead of gobbling up platelets, the macrophages attack some of the body’s many red blood cells.

This allows platelets to build up to more normal levels in your bloodstream.

WinRho SDF usually starts to work within 1 to 2 days. Platelet levels rise and can stay elevated for a month or more after each dose. Your doctor will determine how many doses of WinRho SDF you need, and how often to give it, based on blood test results.5,6

Effectiveness of WinRho SDF†

More than 80% of children with acute ITP responded to WinRho in a medical study. The response rates were comparable to those seen with corticosteroids and IVIG.5,6

In a study of children with chronic ITP, 79% responded. WinRho was effective in 88% of adults with chronic ITP.5,6

†WinRho has been used for the treatment of ITP for over 15 years. These studies were done using earlier formulations of the product. The current formulation is considered to be biologically equivalent to the earlier formulations.

Please see pages 14-15 for Important Risk Information and Boxed Warning.

Please see accompanying WinRho SDF Prescribing Information for full prescribing details.
Administering **WinRho® SDF**

[Rh\(O(D)\) Immune Globulin Intravenous (Human)]

WinRho SDF is given through a needle inserted into a vein. It may take as few as 3 to 5 minutes to receive an entire dose. This can be done in your doctor's office, a clinic, or a hospital.\(^5\,^6\) Due to the risk of IVH, patients should be observed closely in a health care setting for 8 hours after a dose of WinRho SDF. It is also important to perform a dipstick urine test to check for blood in the urine.

**WARNING: INTRAVASCULAR HEMOLYSIS (IVH)**

Intravascular hemolysis (IVH) leading to death has been reported in patients treated for immune thrombocytopenic purpura (ITP) with WinRho SDF.

IVH can lead to clinically compromising anemia and multi-system organ failure including acute respiratory distress syndrome (ARDS).

Serious complications including severe anemia, acute renal insufficiency, renal failure and disseminated intravascular coagulation (DIC) have also been reported.

Closely monitor patients treated with WinRho SDF for ITP in a healthcare setting for at least eight hours after administration. Perform a dipstick urinalysis at baseline, 2 hours, 4 hours after administration, and prior to the end of the monitoring period. Alert patients and monitor the signs and symptoms of IVH including back pain, shaking chills, fever, and discolored urine or hematuria. Absence of these signs and/or symptoms of IVH within eight hours do not indicate IVH cannot occur subsequently. If signs and/or symptoms of IVH are present or suspected after WinRho administration, post-treatment laboratory tests should be performed including plasma hemoglobin, haptoglobin, LDH, and plasma bilirubin (direct and indirect).

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Please see accompanying WinRho SDF Prescribing Information for full prescribing details.
Possible side effects of WinRho SDF

The most common side effects of WinRho SDF are: headache, chills, and fever. Each of these side effects occurred with approximately 2% of doses in medical studies.\(^5\)

Because of the way it works, WinRho SDF can cause a drop in hemoglobin, the oxygen-carrying substance in your blood. While you are taking WinRho SDF, your doctor will routinely check your blood to make sure you are not becoming anemic.\(^5\)

Intravascular hemolysis (IVH) is a much less common but potentially serious side effect. The signs of IVH may include back pain, shaking chills, and discolored (pink or red) urine. If any of these symptoms occurs after a dose of WinRho, report it to your health care provider immediately.\(^5\)
Outlook for patients with ITP

The outlook for patients with ITP is quite favorable. Life-threatening bleeding is rare but precautions should be taken to prevent injury.\textsuperscript{1,3}

Ask your doctor which sports or activities are permissible. When participating in any sport, be sure to wear appropriate safety gear.

ITP goes away within 6 months in the majority of children who have it. Chronic ITP can usually be effectively controlled with one of the treatments described in this booklet.\textsuperscript{1,3}

For more information on ITP, contact the following organizations:

**ITP Foundation**  
30 Old Kings Highway South, Suite 275  
Darien, CT 06820  
(203) 655-6954  
www.itpfoundation.org

**Platelet Disorder Support Association (PDSA)**  
133 Rollins Avenue, # 5  
Rockville, MD 20852  
1-87-PLATELET (1-877-528-3538)  
www.pdsa.org

**Children’s Cancer & Blood Foundation**  
333 East 38th Street  
Suite 830  
New York, NY 10016  
(212) 297-4336  
www.childrenscbf.org

Please see pages 14-15 for Important Risk Information and Boxed Warning.  
Please see accompanying WinRho\textsuperscript{©} SDF [Rho(D) Immune Globulin Intravenous (Human)] Prescribing Information for full prescribing details.
Glossary

**Anemic**: Having low levels of hemoglobin, the substance that carries oxygen in the blood

**Antibodies**: Substances produced by the immune system to specifically attack potential threats, such as viruses or bacteria

**Anti-D immune globulin**: A type of immune globulin containing antibodies against a specific protein found on red blood cells

**Autoimmune disorder**: A condition in which the immune system mistakes cells in a person’s own body for a threat and attacks them

**Corticosteroids**: A class of drugs used to reduce inflammation that is based on hormones secreted by the body

**Immune globulin**: A type of medication containing antibodies derived from human blood

**ITP**: An abbreviation for immune thrombocytopenic purpura, a blood disorder that can cause abnormal bleeding or bruising

**Intravascular hemolysis**: The rupture of a large number of red blood cells in the bloodstream

**Macrophage**: A “scavenger” cell in the immune system that engulfs and destroys debris and foreign substances

**Off-label**: Not used for a condition or in a manner approved by the Food and Drug Administration (FDA).

**Plasma**: The liquid portion of the blood

**Platelets**: Small cells that help the blood to clot and prevent bleeding (also known as thrombocytes)

**Purpura**: Purplish appearance of the skin due to abnormal bruising or bleeding

**Red blood cells**: The cells in the blood that are responsible for transporting oxygen through the body

**Spleen**: An organ in the abdomen that stores blood, destroys old blood cells, filters foreign substances from the blood, and produces some cells of the immune system

**Thrombocytopenia**: A condition characterized by low numbers of blood-clotting cells called platelets

For more information about WinRho SDF, please visit www.winrho.com or call 1-800-4-WINRHO (1-800-494-6746).
Indications and Usage

**WinRho® SDF** [Rh(D) Immune Globulin Intravenous (Human)] must be administered via the intravenous route when used in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomized, Rh(D)-positive:

- children with chronic or acute ITP,
- adults with chronic ITP, or
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The safety and efficacy of **WinRho SDF** has not been evaluated in clinical trials for patients with non-ITP causes of thrombocytopenia or in previously splenectomized patients or in patients who are Rh(D)-negative.

**WinRho SDF Liquid is Bioequivalent to WinRho SDF Lyophilized**

In two comparative pharmacokinetic studies (n=101), the formulations were bioequivalent following IV administration based on the area under the curve to 84 days and had comparable pharmacokinetics following IM administration. Both formulations also had similar elimination half-lives. **WinRho SDF** must be administered via the intravenous route for the treatment of ITP.

**Important Risk Information**

**WARNING: INTRAVASCULAR HEMOLYSIS (IVH)**

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- patients with autoimmune hemolytic anemia
- patients with pre-existing hemolysis or in patients at high risk for hemolysis
- patients who are IgA deficient with antibodies against IgA

The liquid formulation of WinRho SDF contains maltose. Maltose in IGIV products has been shown to give falsely high blood glucose levels in certain types of blood glucose testing systems. Due to the potential for falsely elevated glucose readings, only testing systems that are glucose-specific should be used to test or monitor blood glucose levels in patients receiving WinRho SDF Liquid.

WinRho SDF is made from human plasma. It may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Use of Immune Globulin Intravenous (IGIV) products, particularly those containing sucrose, have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephropathy, and death. WinRho SDF does not contain sucrose. For patients at risk of renal dysfunction or failure, administer WinRho® SDF at the minimum infusion rate practicable.

In Rh(D)-positive patients with ITP, side effects related to the destruction of Rh(D)-positive red blood cells, most notably a decrease in hemoglobin, can be expected. In most cases, the red blood cell destruction is believed to occur in the spleen.

Thrombotic events may occur following treatment with WinRho SDF and other IGIV products.

- Noncardiogenic pulmonary edema [transfusion-related acute lung injury (TRALI)] may occur in patients following IGIV treatment.

General adverse reactions associated with the use of WinRho SDF include body weakness, abdominal or back pain, low blood pressure, paleness, diarrhea, abnormal blood work, joint pain, muscle pain, dizziness, abnormal movement, sleepiness, itchiness, rash, and sweating. In the treatment of ITP, the most common adverse events (≤ 2% of infusions) were headache, chills, and fever.

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In Rho(D)-positive patients with ITP, side effects related to the destruction of Rho(D)-positive red blood cells, most notably a decrease in hemoglobin, can be expected. In most cases, the red blood cell destruction is believed to occur in the spleen.

Thrombotic events may occur. Patients may experience signs and symptoms of pulmonary embolism, deep vein thrombosis, stroke, and/or transient ischemic attack.

Noncardiogenic pulmonary edema [transfusion-related acute lung injury (TRALI)] may occur in patients following IGIV treatment.

General adverse reactions associated with the use of WinRho SDF include body weakness, abdominal or back pain, low blood pressure, paleness, diarrhea, abnormal blood work, joint pain, muscle pain, dizziness, abnormal movement, sleepiness, itchiness, rash, and sweating. In the treatment of ITP, the most common adverse reactions were headache, chills, and fever.

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