

## Important Safety Information

### WinRho® SDF [Rh<sub>0</sub> (D) Immune Globulin Intravenous (Human)]

WinRho® SDF 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<sub>0</sub>(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® have 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<sub>0</sub>(D) negative.

### IMPORTANT SAFETY INFORMATION

Individuals known to have severe, potentially life-threatening reaction to human globulin should not receive WinRho® SDF or any other immune globulin (Human). Individuals who are deficient in IgA may have the potential for developing IgA antibodies and have severe, potentially life-threatening allergic reactions.

**Physicians should alert the patients who are being treated with WinRho® SDF about the signs and symptoms consistent with intravascular hemolysis that include back pain, shaking chills, fever and discolored urine occurring, in most cases, within four hours of administration. Potentially serious complications of intravascular hemolysis that have also been reported include clinically compromising anemia, acute renal insufficiency or disseminated intravascular coagulation (DIC) that have, in some cases, been fatal. The extent of risk of intravascular hemolysis and its complications is not known but is reported to be rare, especially for DIC, which is very rare.**

**The liquid formulation of WinRho® SDF contains maltose. Maltose in IVIG 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.

WinRho® SDF must be administered via the intravenous route for the treatment of ITP.

WinRho® SDF should not be administered to Rh<sub>0</sub>(D) -negative or splenectomized individuals as its efficacy in these patients has not been demonstrated.

In Rh<sub>0</sub>(D) -positive patients with ITP, side effects related to the destruction of Rh<sub>0</sub>(D)-positive red blood cells, most notably a decreased hemoglobin, can be expected. In most cases, the red blood cells destruction is believed to occur in the spleen. However, signs and symptoms consistent with intravascular hemolysis (IVH), including back pain, shaking chills, and/or pink urine, have been reported. Other less common reactions include death, rapid or worsening of anemia, and rapid or worsening of kidney function.

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 ( $\leq 2\%$  of infusions) were headache, chills, and fever.

Please review the [Full Prescribing Information](#).