Other Names	• Rh (D) Immune Globulin • WinRho SDF
Description	• Sterile liquid gamma globulin (IgG) fraction prepared from pooled human plasma containing antibodies to Rh D) antigen (D antigen). • Viral reduction steps include filtration, and solvent/detergent treatment. • One 1500 IU (300 µg) vial contains sufficient anti-Rh(D) to effectively suppress the immunizing potential of approximately 15 mL of Rh (D) (D-positive) packed red blood cells (30 mL of Rho(D) (D-positive) whole blood). • Latex-free

Special Approvals/authorizations	• An independent 2-person check is required for all doses, as per Canadian Blood Services.
	• **Samples for Rh testing must be collected prior to release of the product by the Blood Bank in the following patients:**
	  ○ Prior to the 26 – 28 week gestation injection
	  ○ One hour post-partum or ASAP
	  ○ Prior to a therapeutic abortion
	  ○ Post-partum specimens are required following
	  ▪ Spontaneous abortion
	  ▪ Ectopic pregnancy
	  ▪ Still birth
	  ▪ Intra-uterine death
	  ▪ Molar “pregnancy”

Classification	**Special Populations:** **Pediatrics (< 16 years of age):** WinRho® has been evaluated in children for the treatment of chronic or acute ITP and in children with ITP secondary to HIV infection. The dosing recommendation in the treatment of children with ITP is the same as in adults. **Pregnancy and Other Obstetric Conditions:** WinRho® SDF, Rho (D) Immune Globulin (Human) is indicated for the prevention of Rh immunization in Rho (D) negative mothers not previously sensitized to the Rho (D) factor. WinRho® SDF is recommended for prevention of Rh immunization of Rho (D) negative women at risk of developing Rh antibodies. Rho (D) Immune Globulin (Human) prevents the development of Rh antibodies in the Rho (D) negative and previously not sensitized mother carrying a Rho (D) positive fetus, thus preventing the occurrence of hemolytic disease in the fetus or the newborn. The administration of WinRho® SDF to women satisfying the above conditions should be done at about 28 weeks' gestation when the child's father is either Rho (D) positive or unknown. WinRho® SDF should be administered within 72 hours after delivery if the baby is Rho (D) positive or unknown. WinRho® SDF administration is also recommended in these same women within 72 hours after spontaneous or induced abortion, amniocentesis, chorionic villus sampling, ruptured tubal pregnancy, abdominal trauma or transplacental hemorrhage, unless the blood type of the fetus or father are confirmed to be Rh (D) negative. It should be administered as soon as possible in the case of maternal bleeding due to threatened abortion. **Geriatrics (> 65 years of age):** No specific precautions necessary.

Indications	**1. Prophylaxis of Rh Hemolytic Disease of the Newborn in Pregnancy** • All Rh-negative mothers at 28-32 weeks gestation, unless they have already formed anti-D. If undelivered after 40 weeks, consider a further prenatal dose. • An Rh-negative woman who currently demonstrates a passive anti-D (due to prior injections) may require another RhIg dose, depending on the diagnosis and how much time has elapsed since the initial injection. • All Rh-negative mothers of Rh positive or weak D (Du) positive babies within 72h of delivery. If more than 72h have elapsed, RhIg should not be withheld, but administered as soon as possible, up to 28 days after delivery. Additional dosing will be recommended if the initial maternal hemorrhage screen is positive and the Kleihauer-Betke test shows greater than 30 mL of fetal-maternal hemorrhage. • All Rh Negative women within 72h of therapeutic abortion, miscarriage, ectopic pregnancy, vaginal bleeding in pregnancy, amniocentesis, abdominal trauma, or external cephalic version. If continued or intermittent bleeding is present, additional doses of RhIg at 3 week-intervals may be indicated (see above). Repeat dosing for additional procedures or risks is recommended if greater than 3 weeks have elapsed since the last dose. **2. Incompatible Blood Transfusions** RhIg should be considered whenever Rh positive platelets are transfused to a pediatric (< 16 years of age) or female (≤ 50 years of age) Rh negative recipient, or when Rh positive red cells **3. Treatment of Immune Thrombocytopenic Purpura** • RhIg may be considered as an alternative to intravenous immune globulin in a non-splenectomised Rh-positive patient only.
Contraindications	**1. Prophylaxis of Rh Immunization** **RhIg should NOT be administered to:** • Rh positive (including babies) patients. • Rh-negative women who are Rh sensitized, and have formed anti-D as evidenced by standard antibody screening tests. • Patients with history of anaphylactic or other severe systemic reaction to immune globulins. • Patients hypersensitive to RhIg or to any component of its formulation. **2. Treatment of ITP** **RhIg should NOT be administered to:** • Rh-negative patients. • Splenectomised patients. • Patients with history of anaphylactic or other severe systemic reaction to immune globulins. • Patients hypersensitive to RhIg or to any component of its formulation. **WARNINGS:** • **WinRho® SDF liquid contains maltose, which can give falsely high blood glucose levels in certain types of blood glucose test systems.** • **Immune globulin administration may impair the efficacy of live attenuated virus vaccines (measles, mumps, rubella, and varicella). Vaccination with live virus vaccines should be deferred until approximately 3 months after administration of WinRho® SDF. Patients who have received WinRho® SDF after live virus vaccination should be re-vaccinated 3 months after the administration of the immune globulin.** • **A decrease in hemoglobin level can occur when using RhIg for the treatment of ITP, since passively administered anti-D attaches to the D antigen on the recipients own red cells. The mean maximum decrease in hemoglobin is approximately 17.0 g/L. Hemoglobin concentration should be monitored in these patients**
Supplied	Vial Size is 600 IU, 1500 IU, 5000 IU

Dosage

	Maximum Single Dose
Idiopathic Thrombocytopenic Purpura	60 mcg/kg Intravenous
Rh-negative women	3000 International Units Intravenous (3000 International Units Intravenous every 8 hours until full dose is given. Refer to product insert.)

	Dosage	**Intravenous**	**Intramuscular**
Idiopathic Thrombocytopenic Purpura	50 mcg/kg (1 dose) If patient's haemoglobin less than 100g/L, dose should be reduced to 25-40 mcg/kg	Yes	No
Rh-negative women without Anti-D antibodies (28 weeks)	1500 International Units	Yes (preferable)	Yes
Rh-negative women without Anti-D antibodies (39-40 weeks)	1500 International Units	Yes (preferable)	Yes
Post-partum dose (If infant is Rh positive or Rh unknown)	1500 International Units (If not given at 39-40 weeks)	Yes (preferable)	Yes
Post termination of pregnancy or spontaneous abortion:	1500 International Units	Yes (preferable)	Yes
Antepartum doses (vaginal bleeding, amniocentesis or abdominal trauma)	1500 International Units Consult the Manitoba Rh program for timing of subsequent doses.	Yes (preferable)	Yes
Note	1 mcg = 5 International Units		

Reconstitution/Stability

Reconstitution

RhIg should be reconstituted only with the accompanying vial of sterile diluent. Use aseptic technique throughout.

1. Reconstitute shortly before use.
2. Remove caps from the diluent and product vials.
3. Wipe exposed central portion of the rubber stopper with suitable disinfectant.
4. Withdraw diluent using a suitable syringe and needle. Use 1.25 to 2.5 mL of sterile diluent for intravenous injection or 1.25 mL for intramuscular injection for 1,500 IU (300 µg). Discard any unused diluent.
5. Inject diluent slowly at an angle so that the liquid is directed onto the inside glass wall of the vial containing the freeze-dried pellet.
6. Wet pellet by gently tilting and inverting the vial. Do not shake. Avoid frothing. Gently swirl upright vial until dissolved (less than ten minutes).
7. The product should be brought to room or body temperature immediately prior to use.

Stability

- Stable at 2-8ºC until the expiry date indicated on the label.
- Do not freeze.
- Must be used immediately following reconstitution. Infusions should be completed within four hours after reconstitution of the product.
- Compatible in normal saline
- Do NOT administer concurrently with any other product

Compatibilities/ Incompatibilities	• Use a separate line with a standard IV administration set (tubing with a filter is not required). • No other drugs / solutions (including normal saline) can be co-administered in the same line while PCC is being infused
Administration, Identification and ABO Compatibility	Refer to **Manitoba Best Practice Guidelines** • section 2.2 Standards- Identification and Administration • section 1.4 for ABO Compatibility
Administration, Method	Maximum Concentration: • Not applicable Maximum Rate: • Intravenous push: 1500 International Units over 5 seconds INTRAVENOUS INTERMITTENT (for ITP): • Add dose to 50-100 mL normal saline and administer over 15-30 minutes INTRAVENOUS PUSH (for obstetrical indications): • Administer undiluted over 5-15 seconds
Adverse Events	Refer to **Manitoba Best Practice Guidelines** section 2.7 for transfusion reactions.
Resources:	For further information on its use in Obstetrics, “Guidelines for pre and post natal testing and administration of Rh Immune Globulin” are available from Canadian Blood Services-Manitoba Rh Program