Alberta Health Services

This document applies to all Covenant and AHS sites.

WinRho® SDF

Class: *Rh_o(D) Immune Globulin (Human)*

OTHER NAMES: Rh_o(D) Immune Globulin (Human), RhIG

Company: Cangene

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes	Yes	No	Yes*	Yes	N/A

*Subcutaneous administration is considered off-label use and may only occur at the direction of the hematologist or Center for Bleeding Disorder physician.

Professionals performing these restricted activities have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently.

DESCRIPTION OF PRODUCT:

- WinRho® is an Rh Immune Globulin (RhIG). It is a sterile liquid gamma globulin (IgG) fraction prepared from pooled human plasma containing antibodies to the Rh_o(D) antigen found on Rh positive red cells.
- Viral reduction steps include filtration, and solvent/detergent treatment.
- One 1500 IU (300 µg) vial contains sufficient anti-D to effectively suppress the immunizing potential of approximately 15 mL of Rh positive packed red blood cells (or 30 mL of Rh positive whole blood).
- Available in sizes of: 600 IU (120 µg), 1500 IU (300 µg), and 5000 IU (1000 µg) single-use vials.
- **Latex-free**
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AVAILABILITY:

- Supplied by CBS
- Contact your local laboratory/transfusion service regarding stock availability on site.
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INDICATIONS FOR USE:

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 should receive routine antenatal prophylaxis with RhIG. If undelivered after 40 weeks, consider a further prenatal dose.
- Routine antenatal prophylaxis with RhIG should be administered regardless of, and in addition to, any RhIG administered for a potentially sensitizing event.
- 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 (D^u) 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 quantitative testing shows greater than 30 mL of fetal-whole blood.
- All Rh Negative women within 72h of a potentially sensitizing event (e.g. therapeutic abortion, miscarriage, ectopic pregnancy, vaginal bleeding in pregnancy, amniocentesis, abdominal trauma, or external cephalic version (ECV)). 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 ≥ 3 weeks have elapsed since the last dose.
- In the event of an intrauterine death (IUD) where no sample can be obtained from the baby, an appropriate prophylactic dose of RhIG should be administered to Rh negative previously unsensitised females within 72 hrs of the IUD diagnosis.

2. Incompatible Blood Transfusions

- Rh negative components should be transfused to all Rh negative females of childbearing potential (< or = to 45 years of age) whenever possible. RhIG should be considered whenever Rh negative females of childbearing potential are exposed to Rh positive red cells. It is generally not necessary to administer RhIG to females without childbearing potential or to males who receive Rh positive components. However, in certain circumstances (e.g. repeated future transfusions anticipated) it may be considered.

3. Treatment of Immune Thrombocytopenic Purpura (ITP)

- RhIG may be considered as an alternative to intravenous immune globulin (IVIG) in a non-splenectomized 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 product or to any component of its formulation.

2. Treatment of ITP

RhIG should **NOT** be administered to:

- Rh negative patients.
- Splenectomized patients.
- Patients with history of anaphylactic or other severe systemic reaction to immune globulins.
- Patients hypersensitive to product 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 product 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.

DOSE:

1. Prophylaxis of Rh Hemolytic Disease of the Newborn in Pregnancy

- 1500 IU (300 µg) is standard dose. If gestational age is known to be less than 20 weeks, a 600 IU (120 µg) dose may be sufficient for a potentially sensitizing event.
- Requests for any other dose will automatically be substituted with the standard dose, and a comment will be placed on the transfusion tag indicating such.

2. Exposure to Rh Positive blood or red blood cells

- Recommended dose = between 45 IU/mL and 120 IU/mL of red cells, depending on route of administration. Patient's specific dose will be recommended by a Transfusion Medicine Physician/Hematopathologist.

3. Treatment of ITP

- Adult recommended initial dose = 125-250 IU/kg (25-50 µg/kg) body weight, depending on the hemoglobin. If the patient has a hemoglobin level of 8-10 g/dL, a reduced dose of 125-200 IU/kg should be considered to reduce the risk of increasing anemia severity.
- Subsequent dosing should be between 125 to 300 IU/kg if required, and should be based on the patient's clinical response by assessing platelet counts, red cell counts, hemoglobin and retic counts.
- Pediatric ITP recommended dose = 375 IU/kg (75 µg/kg) body weight.

ADMINISTRATION:

Ensure patient consent has been obtained prior to requesting blood product from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per protocol.

- Visually inspect for particulate matter and discoloration prior to administration.
- Bring to room temperature immediately before administration.
- Current ABO/Rh testing and antibody screen results will be required prior to issue.
- For perinatal patients for whom no Canadian Blood Services (CBS) results or report for the current pregnancy is available, a sample of blood for ABO/Rh will be required prior to the issue of product. The product may be administered prior to receipt of results.

1. Prophylaxis of Rh Hemolytic Disease of the Newborn in Pregnancy

- IM/IV as per institutional policy.
- Recommended IV rate = 1500 IU (300 µg)/5-15 seconds.
- Recommended IM rate = as tolerated by the patient

2. Exposure to Rh Positive blood or red blood cells

- IM/IV as per institutional policy.
- Recommended IV: 3000 IU (600 µg) q8h until total dose administered. Rate = 1500 IU (300 µg)/5-15 seconds.
- Recommended IM: 6000 IU (1200 µg) q12h until total dose administered.

3. Treatment of ITP

- Recommended IV at a rate of 1500 IU (300 µg)/5-15 seconds.
- Recommended SC rate over a period of 3-5 minutes as tolerated by patient. Rate to be specified by hematologist or Center for Bleeding Disorder physician

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) should be reported to your local transfusion service.
- **The most commonly reported adverse reactions are pain at the injection site, headache, chills, fever, nausea, vomiting, arthralgia, moderate low back pain, rash.**

Side Effects	→	**Action**
- Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→	Slow rate of infusion

Potential Allergic Reaction	→	**Action**
- Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→	**STOP** infusion **IMMEDIATELY** and contact physician

NURSING IMPLICATIONS:

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, see the following link: http://www.albertahealthservices.ca/4240.asp.

Patient Monitoring:

- Vital Signs: Pre-administration and at least 20 min. post-dose for any adverse effects.

ITP patients:

- Dipstick urinalysis: pre-dose; 2h, and 4h-post dose; and at the end of the monitoring period.
- Following product administration, ITP patients should be monitored for at least 8h post-administration for signs/symptoms and of intravascular hemolysis and its complications, including:
  - Hemoglobinuria
  - Pallor
  - Hypotension
  - Tachycardia
  - Oliguria or anuria
  - Edema
  - Dyspnea
- Patients should be instructed to **immediately** report symptoms of back pain, discolored urine, decreased urine output, sudden weight gain, fluid retention/edema and/or shortness of breath to their physicians.
- ITP patients presenting with signs and/or symptoms of intravascular hemolysis and its complications after product administration should have confirmatory lab testing, including:
  - CBC
  - Haptoglobin
  - Plasma hemoglobin
  - Urinalysis
  - Renal function tests
  - Liver function tests
  - DIC specific tests

Side Effects:

- Swelling at injection site, fever (IM administration).
- Headache, chills, fever, decrease in hemoglobin (treatment of ITP)

Documentation:

- The transfusion documentation should be double signed (where required) to indicate infusion. Document start and stop date and time of transfusion.
- Assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper) as required.
- ***Recipients of blood products are to be notified in writing of the transfusion***

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-8°C. **Do not freeze**.
- Expiration date is indicated on bottle and packaging.

COMMENTS:

Date Effective: 26 Feb 2016
Revised Date: 23 Feb 2016
Version: 1.1
Approved By: Transfusion Medicine Network
Document Number: PTMGNR00019
For questions or comments, please contact transfusion.safetyteam@albertahealthservices.ca

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