ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

WinRho®
Rh Immune Globulin (Human)

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***OTHER NAMES:*** *RhIG, Rho Immunoglobulin* ***Company:*** *Saol Therapeutics Research Ltd. (Emergent BioSolutions Canada)* ***Class:*** *Manufactured blood product, derived from human plasma*

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

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**
**** Subcutaneous administration is considered off-label use and may only occur at the direction of the hematologist or Center for Bleeding Disorders physician.**

DESCRIPTION:

- WinRho® is a sterile liquid gamma globulin (IgG) fraction prepared from pooled human plasma containing antibodies to the RhD antigen (D antigen) prepared using an anion-exchange column chromatography method.
- Viral inactivation/removal steps include filtration, anion exchange, and solvent/detergent treatment.
- Maximum immunoglobulin A (IgA) concentration is 40 mcg/mL.
- Available in 600 IU (120mcg), 1500 IU (300mcg), and 5000 IU (1000 mcg) single use vials.
- Also contains maltose and Polysorbate 80. May contain trace amounts of tri-n-butyl and octoxynol.
- Preservative-free.
- Latex-free.

AVAILABILITY:

- Supplied by Canadian Blood Services
- Contact your local transfusion medicine laboratory regarding stock availability on site.

INDICATIONS:

1. **Prophylaxis of Rh Hemolytic Disease of the Fetus and Newborn (HDFN)**
   - **During Pregnancy:**
     - Indicated for the prevention of Rh immunization in pregnant Rh negative patients, who are not previously sensitized to Rh and are at risk of developing Rh antibodies.
     - All pregnant Rh negative patients who have not already formed anti-D should receive RhIG:
       - As routine prophylaxis at 28-32 weeks gestation. This dose should be given in addition to any RhIG administered for a potentially sensitizing event.
       - 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)). Repeat dosing for additional procedures or risks is recommended if 3 or more weeks have elapsed since the last dose.
       - At 3-week intervals, if continued or intermittent bleeding is present.
     - A pregnant Rh negative patient who demonstrates a passive anti-D from prior injections may require another RhIG dose, depending on the diagnosis and how much time has elapsed since the initial injection.
     - If undelivered after 40 weeks, consider a further prenatal dose.
   - **Post-Partum**
     - All Rh negative postpartum patients who have not already formed anti-D should receive RhIG within 72h of delivery of an Rh positive or weak D positive baby.
     - If more than 72h have elapsed, RhIG should not be withheld, but administered as soon as possible, up to 28 days after delivery.
     - In the event of an intrauterine fetal demise (IUFD) where no sample can be obtained from the baby, an appropriate prophylactic dose of RhIG should be administered within 72 hours of the IUFD diagnosis.

INDICATIONS cont'd

2. RhD Incompatible Blood Component Transfusions

- Rh negative blood components should be transfused to all Rh negative patients with childbearing potential (up to 45 years of age) whenever possible.
- RhIG should be considered whenever Rh negative patients with childbearing potential are exposed to Rh positive blood components.
- It is generally not necessary to administer RhIG to patients without childbearing potential who receive Rh positive components. However, in certain circumstances (e.g. repeated future transfusions anticipated) it may be considered. TM Physician consult is recommended.

3. Treatment of Immune Thrombocytopenic Purpura (ITP)

- RhIG may be considered as an alternative to intravenous immune globulin (IVIG) for treatment of destructive immune thrombocytopenia when platelet counts must be increased to control bleeding.
- Indicated in a non-splenectomized, Rh positive patient **only**.

CONTRAINDICATIONS:

- Patients who are hypersensitive to human immune globulin, or any ingredient in the formulation or component of the container.
- IgA deficiency when the patient has antibodies against IgA **and** a history of hypersensitivity (can result in severe anaphylactic reaction).

1. Prophylaxis of Rh Immunization

RhIG should **NOT** be administered to:

- Rh positive patients.
- Rh negative patients with childbearing potential who are Rh sensitized, and have formed anti-D as evidenced by standard antibody screening tests.

2. Treatment of ITP

RhIG should **NOT** be administered to:

- Rh negative patients.
- Splenectomized patients.
- Patients with ITP secondary to other conditions (e.g. Leukemia, lymphoma, active viral infection).
- Patients at increased risk of complications of acute hemolytic reaction (eg. cardiac, renal, hepatic co-morbidities).
- Patients with evidence of autoimmune hemolytic anemia.

WARNINGS:

- WinRho® SDF liquid contains maltose, which can give falsely high blood glucose levels in certain types of blood glucose test systems.
- May impair the efficacy of live attenuated virus vaccines. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.
- 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:

- One 1500 IU 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.
- Dose must be specified by the MRHP.
- Note: 1mcg = 5 IU

Indication	Situation	Recommended Dose
Prophylaxis of Rh HDFN	Prenatal – 28-week routine prophylaxis	1500 IU (300mcg)
	Sensitizing event - less than 20 weeks gestation	600 IU (120 mcg) dose may be sufficient for a potentially sensitizing event.
	Sensitizing event - Postpartum or greater than 20 weeks gestation	▪ Fetal-maternal hemorrhage testing is required to determine the dose. ▪ A 1500 IU (300 mcg) standard dose may be given prior to the completion of quantitative testing, and the remaining dose (if required) given once the volume of bleed is determined. o IV administration: 45 IU (9mcg) per mL fetal blood detected o IM administration: 60 IU (12 mcg) per mL fetal blood detected
Exposure to Rh positive blood or blood components	Patient-specific dose will be recommended by a Transfusion Medicine Physician.	
	IV administration:	90 IU (18 mcg) per mL RhD Positive RBC exposure. (45IU per mL for whole blood exposure)
Treatment of ITP	Adult - Initial dose	▪ 125-250 IU/kg (25-50 mcg/kg) body weight, depending on the hemoglobin. ▪ If the patient has a hemoglobin level of 80-100g/L, a reduced dose of 125-200 IU/kg should be considered to reduce the risk of increasing anemia severity.
	Adult - Subsequent dose	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	375 IU/kg (75 mcg/kg) body weight.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion:

- Ensure recent patient weight and height is on file.
- Ensure pertinent labs are available as required (ie. ABORH and antibody screen). If results are not available, ensure a specimen is drawn. RhIG may be given prior to receipt of results.
- Ensure any ordered premedications have been given (antihistamines, antipyretics prn).
- Perform pre-transfusion checks per AHS Transfusion of Blood Components and Blood Products Policy.
- Report any new onset acute illness to MD/authorized prescriber prior to commencing infusion.

Access:

- WinRho® can be given via peripheral or central venous access site, or intramuscular injection (route depends on the clinical indication).
- Note: a filter is not necessary, but if used, a pore size of 15 microns or larger will be less likely to slow infusion. 0.2 micron filters may be used.

Compatible IV Solutions:

- Compatible with normal saline.
- Do not mix with other products, medications, or solutions.

ADMINISTRATION cont'd:

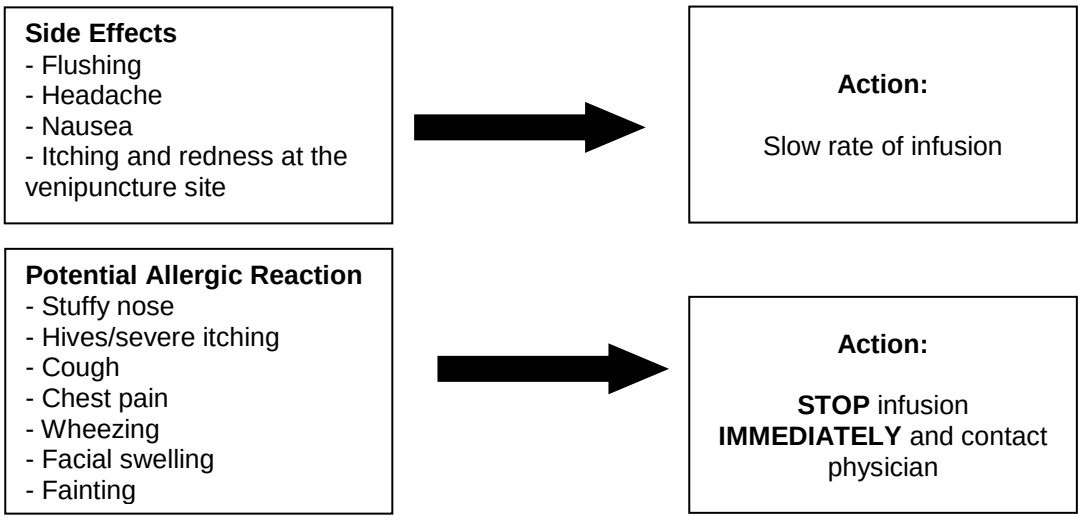
Administration:

- Bring WinRho® to room temperature immediately prior to use.
- Visually inspect the product prior to administration. Do not use products that are cloudy or contain particulates.
- Administration rate must be specified by the MRHP.
- **IV Administration:**
  - **Option 1:** Administer via Direct IV. Flush using normal saline.
  - **Option 2:** Transfer to Minibag
    - Inject WinRho® into the minibag.
    - Infuse the prescribed amount at the appropriate rate.
    - Flush using normal saline.
- **Administration rate:**

Indication	Route	Recommended Infusion Rate
Prophylaxis of Rh HDFN in Pregnancy	IV	1500 IU (300 mcg) over 5-15 seconds.
	IM	1500 IU (300 mcg) as tolerated by the patient.
Exposure to Rh Positive blood or blood components	IV	3000 IU (600 mcg) every 8 hours until total dose administered. Recommended rate of 1500 IU (300 mcg) over 5-15 seconds.
Treatment of ITP	IV	1500 IU (300 mcg) over 5-15 seconds.
	SC	As specified by hematologist or Centre for Bleeding Disorders Clinic. Recommended over a period of 3-5 minutes as tolerated by patient.

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 to RhIG are pain and swelling at the injection site, headache, chills, fever, nausea, vomiting, arthralgia, moderate low back pain, rash.
- Headache, chills, fever, decrease in hemoglobin may also occur with treatment of ITP.



NURSING IMPLICATIONS:

Patient Vital Signs and Monitoring:

- Vital Signs: Pre-administration and at least 20 min. post-dose for any adverse effects.
- If the patient has experienced previous adverse reaction to product, or this is the first infusion of product for patient, monitor for 30-60 minutes post.

ITP patients:

- Instruct the patient to **immediately** report symptoms of back pain, discolored urine or hematuria, decreased urine output, shaking, chills, fever, sudden weight gain, fluid retention/edema and/or shortness of breath. The patient should monitor for these symptoms for at least 72 hours.
- Monitor patient for at least 8 hours post-administration for signs and symptoms and of intravascular hemolysis and its complications, including hemoglobinuria, pallor, hypotension, tachycardia, oliguria or anuria, edema, or dyspnea.
- **Laboratory Monitoring**:
  - Urinalysis dipstick: pre-dose; 2h, 4h-post dose, and at the end of the monitoring period.
  - ITP patients presenting with signs and symptoms suggestive of intravascular hemolysis should have confirmatory lab testing.

Note: Vital signs/patient monitoring may be conducted more frequently as determined by clinical condition of patient.

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, go to http://www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- Ensure documentation is completed per the AHS Transfusion of Blood Components and Blood Products Policy
- Patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification documentation where required.
- Patient Resource *When You Need Rh Immune Globulin* available from myhealth.alberta.ca

STORAGE & STABILITY

- Store at 2-8°C until expiry.
- Protect from light.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES

Saol Therapeutics Research Limited. Aug 2021. WinRho® SDF Product Monograph. Submission Control 253537. [Accessed 1Dec21] https://winrho.com/pdfs/WinRho-PM_EN_3August2021.pdf

CSA. Blood and Blood Components. National Standard of Canada. CAN/CSA-Z902:20. Ottawa, ON. Standards Council of Canada; 2020.

CPSA. Standards for Diagnostic Laboratory Accreditation: Transfusion Medicine v9 April 2021.

Blood products, human immunoglobulin and timing of immunization: Canadian Immunization Guide. Government of Canada. January 2020. [Accessed 1Feb22] https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-11-blood-products-human-immune-globulin-timing-immunization.html