

Section S: Blood Product Overview – WinRho® Rh Immune Globulin (Rhlg) Cangene

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DESCRIPTION of PRODUCT

- Derived from human plasma containing high titre antibodies to Rh_o (D).
- The gamma globulin (IgG) fraction of the human plasma is prepared by anion-exchange column chromatography
- Viral inactivation steps include the use of Solvent Detergent treatment and filtration
- Potency of the product is now expressed in International Units (IU), previously expressed as µg (1µg = 5 IU). 1500 IU (300 µg) is sufficient anti-D to effectively suppress the immunizing potential of approximately 17 mL of Rh Positive red cells.
- Rhlg is usually provided in a LIQUID formulation, which is stabilized with 10% maltose and 0.03% (w/w) polysorbate 80. It does not contain any preservatives (including thimerosal) and is latex free.
 - See product insert for reconstitution instructions if LYOPHILIZED product is provided, or refer to [Administration of Product](#) section below.

AVAILABILITY of PRODUCT

- The following vial sizes are available:

µg	IU	mL
120 µg	600 IU	0.5 mL
300 µg	1500 IU	1.3 mL
1000 µg	5000 IU	4.4 mL

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STORAGE of PRODUCT

- Stored at 2 - 8°C. Do NOT freeze.
- Expiration date is indicated on package.
- LYOPHILIZED formulation must be administered within 4 hours of reconstitution. Do NOT refrigerate reconstituted product.

CLINICAL INDICATIONS (see [product monograph](#) or package insert for contraindications)

- To prevent the formation of anti-D in Rh (D) Negative females who are < 50 years of age, after the exposure to Rh (D) Positive Red Cells. A 1500 IU (300µg) vial of Rhlg is recommended for exposure of up to 17mL Rh Positive Red Cells. See [product monograph](#) or package insert for additional dose recommendations.
 - The exposure may be due to fetal maternal hemorrhage (during pregnancy, at delivery or abortion, due to amniocentesis or abdominal trauma) or transfusion of blood products containing red cells (e.g. platelets)
- Rhlg may also be given to Rh (D) Positive patients with Immune Thrombocytopenic Purpura (ITP). Will cause hemolysis; patient must be carefully monitored. See Cangene Notice: [“Association of WinRho with intravascular hemolysis in the treatment of ITP – Important new prescribing information.”](#)

REQUESTS for Rhlg

- ABO/Rh Group and antibody screening must be tested (within the previous month) before the Rhlg is issued.
- Southwestern Ontario Rh Program recommendations for the use of Rhlg in obstetrical patients are summarized in the chart below:

Obstetrical situation		Dosage
Loss of pregnancy (Abortion, ectopic)	Before 16 weeks gestation	120µg
	16 or more weeks gestation	300µg
Threatened abortion Vaginal bleeding or Abdominal trauma	Before 10 weeks gestation	None
	10 or more weeks gestation (dose repeated every 12 weeks until delivery)	300µg
Following amniocentesis, PUBS or CVS (<i>Dose repeated every 12 weeks until delivery</i>)		300µg
Antenatal prophylaxis (<i>Ideally given at 28 weeks</i>)		300µg
After stillbirth		300µg
After delivery of Rh positive baby	Standard dose	300µg
	Postnatal FMH screen indicates additional Rhlg required	As recommended by the BTL

- Refer to the [South Western Ontario Rh Program](#) “Guidelines for Antenatal Antibody Screening and Rh Sensitization Prophylaxis” for additional information.

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ADMINISTRATION of PRODUCT

1. If LIQUID formulation received, no additional preparation is required
2. If LYOPHILIZED formulation, Rhlg must be reconstituted using the diluent provided.
 - Withdraw appropriate amount of diluent using a suitable syringe and needle.
 - *IM injection*: reconstitute both the 1500 IU (300ug) and the 600IU (120ug) with 1.25 mL of diluent.
 - *IV infusion*: reconstitute with 2.5 mL of diluent.
 - 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.
 - Wet pellet by gently tilting and inverting the vial. Do not shake. Avoid frothing. Gently swirl upright vial until dissolved.

Obstetric Indications:

1. Rhlg may be given intramuscularly (IM) or intravenously (IV)
2. IM: Intramuscular injections are made into the deltoid muscle of the upper arm or the anterolateral aspects of the upper thigh. Due to the risk of sciatic nerve injury, the gluteal regions should not be used as a routine injection site. If the gluteal region is used, use only the upper outer quadrant.
3. IV administration of Rhlg should only be done in a hospital setting when physician is on site and available by pager. Does NOT require in-line filter or blood administration set.
 - *IV Push*: Administer in a suitable vein with a rate of injection of 5 to 15 seconds per dose of 1500IU (300ug)
 - *IV Infusion*: Dilute 1500IU (300ug) of Rhlg in 50mL of saline. Infuse over 30 minutes.
4. Entire vial should be administered to deliver the amount specified on label

Following transfusion of Rh Pos blood products (e.g. platelets):

1. BTL will recommend Rhlg for Rh Negative females less than 50 years of age, when they have received an Rh Positive blood product (usually platelets)
2. 300ug is standard dose
3. Rhlg may be given intramuscularly (IM) or intravenously (IV), although if patient is thrombocytopenic, it is recommended that IM injection be avoided
4. IV administration of Rhlg should only be done in a hospital setting when physician is on site and available by pager. Does NOT require in-line filter or blood administration set.
 - *IV Push*: Administer in a suitable vein with a rate of injection of 5 to 15 seconds per dose of 1500IU (300ug)
 - *IV Infusion*: Dilute 1500IU (300ug) of Rhlg in 50mL of saline. Infuse over 30 minutes.
5. Vital signs should be monitored pre and post infusion

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Immune Thrombocytopenic Purpura (ITP):

1. BTL will supply required amount of Rhlg in 50mL of saline.
2. Infuse entire volume in approximately 30 minutes. (If using an infusion pump it can be set for 50mL/30min). Does NOT require in-line filter or blood administration set.
3. Continue to infuse normal saline to keep vein open for 2 hours
4. 2 hours following infusion of Rhlg, check vital signs and urine dipstick test*.
If vital signs OK, patient has no complaints and urine dipstick is negative*, patient may leave clinic area but must remain in hospital. Keep IV saline lock. Have patient return to IV Therapy Clinic at 4 hours post-infusion.
5. At 4 hours, check vital signs and urine dipstick test*.
If vital signs OK, patient has no complaints and urine dipstick is negative, patient may leave clinic area but must remain in hospital. Keep IV saline lock. Instruct patient as to where she/he should go for the 8 hour check.
6. At 8 hours, check vital signs and urine dipstick test*.
If vital signs are okay, patient has no complaints, and urine dipstick test* is negative, remove IV saline lock and patient may leave clinic area and hospital.

* A positive urine dipstick test for blood, bilirubin or urobilinogen may indicate hemolysis and further assessment and work-up is required at the discretion of the treating physician.

LINK to WEBSITE for PRESCRIBING INFORMATION

Product monograph available at

<http://www.winrho.ca/healthcare/pdf/WinRho%20Canadian%20Product%20Monograph%202010-03-12.pdf>