**Other Names**  
WinRho®, SDF, RhoGam, Rhlg

**Consent Required**  
Yes

**Pre-Transfusion Sample**  
☒ Not Required  
Prescriber must have documentation of patient’s Rh status.  
For perinatal applications, the prescriber must have documentation that the Rh-negative mother has not already formed anti-D.

**Approval Requirements**  
For ITP patients, RhIg must be ordered by Clinical Hematologist.

**Product Description**  
Sterile liquid gamma globulin prepared from pooled human plasma containing antibody to Rh₀ (D) antigen. Solvent-detergent treated and filtered to reduce viral transmission. Contains no preservatives.

For intravenous or intramuscular injection. May result in detectable passive anti-D in patient’s serum.

Supplied in 600 IU (120 mcg), 1500 IU (300 mcg) and 5000 IU (1000 mcg) vials.

For all indications except ITP, RhIg is usually supplied in the undiluted form. For ITP, it is filtered and diluted with normal saline into a mini bag in Transfusion Medicine.

**Clinical Indications**

**Perinatal:**  
Recommended for prevention of Rh immunization of Rh negative women at risk of developing Rh antibodies. Rhlg prevents the development of Rh antibodies in the Rh negative and previously non-sensitized woman carrying an Rh positive fetus, thus reducing the likelihood of hemolytic disease in an Rh positive fetus in future pregnancies.

- Indicated in Rh negative women and administered within 72 hours:
  - After delivery if the baby is Rh positive or unknown.
  - Indicated in Rh negative women and administered within 72 hours in the following situations when the fetus is Rh positive or unknown
    - spontaneous or induced abortion at any gestation
    - maternal bleeding due to threatened abortion
    - amniocentesis or chorionic villus sampling
    - ruptured tubal pregnancy
    - abdominal trauma
    - any obstetrical manipulation which may cause transplacental hemorrhage
  - Antepartum at 28 weeks gestation when the fetus is Rh positive or unknown.

**Transfusion:**  
Rhlg is recommended for the suppression of Rh alloimmunization in Rh negative patients transfused with Rh positive platelets.

**Immune Thrombocytopenic Purpura (ITP):**  
Intravenous Rhlg may be used in the treatment of ITP in non-splenectomized Rh positive patients. However, there is a risk of hemolysis and fatalities have been reported. The use of Rhlg for ITP should only be considered after consultation with Clinical Hematology:

- Children with chronic or acute ITP
- Adults with chronic ITP
- Children and adults with ITP secondary to HIV infection

Monitor for clinical response by assessing platelet count, red cell counts, hemoglobin and reticulocyte levels.
## Contraindications

### Prophylaxis of Rh Immunization (Perinatal or Transfusion Indications):

**RhIg should not be administered to patients:**
- Who are Rh positive (including babies)
- Rh negative females who have already formed Anti-D
- With a history of anaphylactic or other severe systemic reaction to human immune globulins
- Who are IgA deficient
- Who are hypersensitive to this drug or to any ingredient in the formulation or component of the container

### Treatment of ITP: RhIg should not be administered to patients:
- Who are Rh negative
- Who are splenectomized
- With ITP secondary to other conditions including leukemia, lymphoma, or active viral infections with EBV (Epstein-Barr virus) or HCV (hepatitis C)
- With evidence of autoimmune hemolytic anemia (Evans Syndrome), or Systemic Lupus Erythematosus (SLE) or anti-phospholipid antibody syndrome (APS)
- With a history of anaphylactic or other severe systemic reaction to human immune globulins
- Who are IgA deficient
- Who are hypersensitive to this drug or to any ingredient in the formulation or component of the container

## Risks

Allergic reactions, chills, fever, headache, pain at IM injection site, transfusion related acute lung injury (TRALI), transmission of infection.

Most serious adverse reactions have been observed in patients receiving RhIg for treatment of ITP and include:
- **Intravascular hemolysis** (decrease in hemoglobin of $\geq 3.0$ g/dL usually occurring within 72 hours following administration). Signs and symptoms include back pain, shaking chills, fever and/or hemoglobinuria occurring, in most cases, within 4 hours of administration. Side effects are related to the destruction of Rh positive red blood cells and can lead to clinically compromising anemia, acute renal insufficiency, disseminated intravascular coagulation (DIC), acute respiratory distress (ARDS)
- **Extravascular hemolysis** (decrease in hemoglobin of $< 3.0$ g/dL usually occurring within 7-14 days following administration)

## Dosage

### Treatment of ITP:
Consult with Clinical Hematology for dosing.

### Transfusion of Rh Positive Platelets to Rh Negative Patients:
- 600 IU (120 mcg) at the time of issue of the first dose of Rh positive platelets.
**BLOOD PRODUCT FACT SHEET**

**Rh IMMUNE GLOBULIN**

### Dosage in Rh Negative Perinatal Patients

The Society of Obstetricians and Gynecologists of Canada has developed clinical practice guidelines surrounding the use of RhIg prophylaxis to help prevent Rh alloimmunization.

<table>
<thead>
<tr>
<th>Routine Antepartum</th>
<th>Dosage / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given at 28 weeks*</td>
<td>1500 IU (300 mcg)</td>
</tr>
</tbody>
</table>

*If RhIG is administered early in the pregnancy (before 28 weeks), it is recommended that it be administered at 12 week intervals in order to maintain adequate levels.

<table>
<thead>
<tr>
<th>Routine Postpartum</th>
<th>Dosage / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery of Rh positive baby</td>
<td>600 IU (120 mcg)</td>
</tr>
<tr>
<td></td>
<td>Within 72 hours after delivery</td>
</tr>
<tr>
<td></td>
<td>If the Kleihauer test for Fetal Maternal Hemorrhage is negative or shows rare fetal cells.</td>
</tr>
<tr>
<td><strong>Note:</strong></td>
<td>If the Fetal Maternal Hemorrhage test is positive the dosage may be adjusted, see below.</td>
</tr>
</tbody>
</table>

#### Positive Fetal Maternal Hemorrhage Test

- The standard IM dose of postpartum Rh Immune Globulin (600 IU [120 mcg]) will cover a fetal maternal hemorrhage volume up to 10 mL of fetal blood. If the Kleihauer test is positive, Transfusion Medicine Laboratory may recommend a 1500 IU (300 mcg) dose if required. More accurate determination of the volume of fetal maternal hemorrhage may also be performed by the flow cytometry test.
- For larger dose requirements of Rh Immune Globulin, the dose will be advised by the Hematopathologist.

<table>
<thead>
<tr>
<th>All Other Clinical Conditions</th>
<th>Dosage / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1500 IU (300 mcg)</td>
<td>Note:</td>
</tr>
<tr>
<td></td>
<td>If the patient is ≥ 20 wks, a Fetal Maternal Hemorrhage test is recommended to determine if dosage needs to be adjusted, except for external cephalic version.</td>
</tr>
</tbody>
</table>

#### Route of Administration

- **If exposed to Rh Positive Blood**
  - Intravenous: 45 IU (9 mcg) / mL of blood
  - Intramuscular: 60 IU (12 mcg) / mL of blood

Administer dose within 72 hours after exposure

- **Via the intravenous route**: 3,000 IU (600 mcg) every 8 hours, until the total dose, calculated from the above table, is administered.
- **Via the intramuscular route**: 6,000 IU (1,200 mcg) every 12 hours, until the total dose, calculated from the above table, is administered.
### BLOOD PRODUCT FACT SHEET

**Rh IMMUNE GLOBULIN**

<table>
<thead>
<tr>
<th>Administration</th>
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<td><strong>Compatible Solution</strong></td>
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<tr>
<td><strong>Perinatal Patients</strong></td>
</tr>
<tr>
<td><strong>Vial Size</strong></td>
</tr>
<tr>
<td>600 IU (120mcg)</td>
</tr>
<tr>
<td>1,500 IU (300mcg)</td>
</tr>
<tr>
<td>2,500 IU (500 mcg)</td>
</tr>
<tr>
<td>5,000 IU (1,000 mcg)</td>
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<tr>
<td>15,000IU (3,000 mcg)</td>
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<tr>
<td><strong>ITP Patients</strong></td>
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<tr>
<td><strong>Storage Conditions</strong></td>
</tr>
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</table>