**HUMAN ANTI-D IMMUNOGLOBIN 250MCG(1250LU)VIAL.**

**CLASS:** Blood Product Derivative; Immune Globulin

**INDICATIONS:** Suppression of Rh isoimmunization: Use in the following situations when an Rho(D)-negative individual is exposed to Rho(D)-positive blood: During delivery of an Rho(D)-positive infant; abortion; amniocentesis; chorionic villus sampling; ruptured tubal pregnancy; abdominal trauma; hydatidiform mole; transplacental hemorrhage. Used when the mother is Rho(D)-negative, the father of the child is either Rho(D)-positive or Rho(D)-unknown, or the baby is either Rho(D)-positive or Rho(D)-unknown.

Transfusion: Suppression of Rh isoimmunization in Rho(D)-negative individuals transfused with Rho(D) antigen-positive RBCs or blood components containing Rho(D) antigen-positive RBCs

Treatment of immune thrombocytopenia (ITP): Used intravenously in the following nonsplenectomized Rho(D)-positive individuals: Children with acute or chronic ITP, adults with chronic ITP, and children and adults with ITP secondary to HIV infection

**AVAILABLE DOSAGE FROM THE HOSPITAL:**

HUMAN ANTI-D IMMUNOGLOBIN 250MCG(1250LU)VIAL, HUMAN ANTI-D IMMUNOGLOBIN 300MCG/1.5ML AMP, HUMAN ANTI-D IMMUNOGLOBIN 300MCG/1.5ML AMP, HUMAN ANTI-D IMMUNOGLOBIN 500 I.U VIAL

**TRADE NAMES:**

**DOSAGE:**

- **Dosing:** Adult

  **ITP:**

  Rhophylac®: I.V.: 50 mcg/kg

  WinRho® SDF: I.V.:

  Initial: 50 mcg/kg as a single injection, or can be given as a divided dose on separate days. If hemoglobin is <10 g/dL: Dose should be reduced to 25-40 mcg/kg

  Subsequent dosing: 25-60 mcg/kg can be used if required to increase platelet count

  Maintenance dosing if patient did respond to initial dosing: 25-60 mcg/kg based on platelet count and hemoglobin concentration

  Maintenance dosing if patient did not respond to initial dosing:

  Hemoglobin <8 g/dL: Alternative treatment should be used

  Hemoglobin 8-10 g/dL: Redose between 25-40 mcg/kg
Hemoglobin >10 g/dL: Redose between 50-60 mcg/kg

Rho(D) suppression: Note: One “full dose” (300 mcg) provides enough antibody to prevent Rh sensitization if the volume of RBC entering the circulation is ≤15 mL. When >15 mL is suspected, a fetal red cell count should be performed to determine the appropriate dose.

**Pregnancy:**

Antepartum prophylaxis: In general, dose is given at 28 weeks. If given early in pregnancy, administer every 12 weeks to ensure adequate levels of passively acquired anti-Rh

HyperRHO™ S/D Full Dose, RhoGAM®: I.M.: 300 mcg

Rhophylac®, WinRho® SDF: I.M., I.V.: 300 mcg

Postpartum prophylaxis: In general, dose is administered as soon as possible after delivery, preferably within 72 hours. Can be given up to 28 days following delivery

HyperRHO™ S/D Full Dose, RhoGAM®: I.M.: 300 mcg

Rhophylac®: I.M., I.V.: 300 mcg

WinRho® SDF: I.M., I.V.: 120 mcg

**Threatened abortion, any time during pregnancy (with continuation of pregnancy):**

HyperRHO™ S/D Full Dose, RhoGAM®: I.M.: 300 mcg; administer as soon as possible

Rhophylac®, WinRho® SDF: I.M./I.V.: 300 mcg; administer as soon as possible

**Abortion, miscarriage, termination of ectopic pregnancy:**


Rhophylac®: I.M., I.V.: 300 mcg

WinRho® SDF: I.M., I.V.: After 34 weeks gestation: 120 mcg; administer immediately or within 72 hours

**Amniocentesis, chorionic villus sampling:**

HyperRHO™ S/D Full Dose, RhoGAM®: I.M.: At 15-18 weeks gestation or during the 3rd trimester: 300 mcg. If dose is given between 13-18 weeks, repeat at 26-28 weeks and within 72 hours of delivery.

Rhophylac®: I.M., I.V.: 300 mcg
WinRho® SDF: I.M., I.V.:
Before 34 weeks gestation: 300 mcg; administer immediately, repeat dose every 12 weeks during pregnancy
After 34 weeks gestation: 120 mcg, administered immediately or within 72 hours
Excessive fetomaternal hemorrhage (>15 mL): Rhophylac®: I.M., I.V.: 300 mcg within 72 hours plus 20 mcg/mL fetal RBCs in excess of 15 mL if excess transplacental bleeding is quantified or 300 mcg/dose if bleeding cannot be quantified

Abdominal trauma, manipulation:
HyperRHO™ S/D Full Dose, RhoGAM®: I.M.: 2nd or 3rd trimester: 300 mcg. If dose is given between 13-18 weeks, repeat at 26-28 weeks and within 72 hours of delivery.
Rhophylac®: I.M., I.V.: 300 mcg within 72 hours
WinRho® SDF: I.M., I.V.: After 34 weeks gestation: 120 mcg; administer immediately or within 72 hours

Transfusion:
HyperRHO™ S/D Full Dose, RhoGAM®: I.M.: Multiply the volume of Rh positive whole blood administered by the hematocrit of the donor unit to equal the volume of RBCs transfused. The volume of RBCs is then divided by 15 mL, providing the number of 300 mcg doses (vials/syringes) to administer. If the dose calculated results in a fraction, round up to the next higher whole 300 mcg dose (vial/syringe).
WinRho® SDF: Administer within 72 hours after exposure of incompatible blood transfusions or massive fetal hemorrhage.
I.V.: Calculate dose as follows; administer 600 mcg every 8 hours until the total dose is administered:
Exposure to Rho(D) positive whole blood: 9 mcg/mL blood
Exposure to Rho(D) positive red blood cells: 18 mcg/mL cells
I.M.: Calculate dose as follows; administer 1200 mcg every 12 hours until the total dose is administered:
Exposure to Rho(D) positive whole blood: 12 mcg/mL blood
Exposure to Rho(D) positive red blood cells: 24 mcg/mL cells
Rhophylac®: I.M., I.V.: 20 mcg per 2 mL transfused blood or 1 mL erythrocyte concentrate.
- **Dosing: Geriatric**
  Refer to adult dosing. Patients >65 years of age with a concurrent comorbid condition (eg, infection, malignancy, autoimmune disorders) may be at increased risk of developing acute hemolytic reactions. Fatal outcomes associated with IVH have occurred most frequently in those >65 years. Careful consideration should be used when selecting dosage for elderly patients due to a higher probability of decreased hepatic, renal, or cardiac function; consider starting at lower doses.

- **Dosing: Renal Impairment**
  I.V. infusion: Use caution; may require infusion rate reduction or discontinuation.

**COMMON SIDE EFFECT:**

Frequency not defined

Cardiovascular: Hyper-/hypotension, pallor, vasodilation

Central nervous system: Chills, dizziness, fever, headache, malaise, somnolence

Dermatologic: Pruritus, rash

Gastrointestinal: Abdominal pain, diarrhea, nausea, vomiting

Hematologic: Haptoglobin decreased, hemoglobin decreased (patients with ITP), intravascular hemolysis (patients with ITP)

Hepatic: Bilirubin increased, LDH increased

Local: Injection site reaction: Discomfort, induration, mild pain, redness, swelling

Neuromuscular & skeletal: Arthralgia, back pain, hyperkinesia, myalgia, weakness

Renal: Acute renal insufficiency

Miscellaneous: Anaphylaxis, diaphoresis, infusion-related reactions, positive anti-C antibody test (transient), shivering

Postmarketing and/or case reports: Anemia (clinically-compromising), anuria, ARDS, cardiac arrest, cardiac failure, chest pain, chromaturia, DIC, edema, erythema, fatigue, hematuria, hemoglobinemia, hemoglobinuria (transient in patients with ITP), hyperhidrosis, hypersensitivity, injection site irritation, jaundice, myocardial infarction, muscle spasm, nausea, pain in extremities, renal failure, renal impairment, tachycardia, transfusion-related acute lung injury

**PREGNANCY RISK FACTORS:** C