UnityPoint Health Pekin
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TRM.40790, TRM.40800, TRM.40780

Rh_o(d) IMMUNE GLOBULIN (HUMAN) HyperRHO® Intramuscular

I. PRINCIPLE

To improve therapy for hemolytic disease of the newborn (HDN). HyperRHO® is a sterile solvent detergent treated Rh_o(D) Immune Globulin Intravenous (Human) solution in a pre-filled, ready-to-use syringe for intramuscular injection. One syringe contains at least 1500 IU (300 µg) of IgG antibodies to Rh_o(D) in a 2.0 mL solution, sufficient to suppress the immune response to at least 15 mL of Rh-positive red blood cells.

HyperRHO® acts by suppressing the immune response of Rh-negative individuals to Rh-positive red blood cells. The risk of immunization is related to the number of Rh-positive red blood cells received and the route of introduction. The Rh-negative obstetrical patient may be exposed to red blood cells from her Rh-positive fetus during the normal course of pregnancy as a consequence of abdominal trauma, amniocentesis, abortion or full-term delivery.

If Administered in time, HyperRHO® S/D Full Dose injection:

- Destroys Rh-positive cells in the mother's body
- Prevents the mother's immune system from producing Rh-positive antibodies
- Protects the baby from contracting Hemolytic Disease of the Newborn, HDN.

II. CLINICAL SIGNIFICANCE

UPH-Pekin Laboratory will utilize HyperRHO®, a sterile solution of Rh_o(D) IgG (also known as anti-D) that can be administered by intramuscular (IM) injection to help prevent the formation of anti- Rh_o(D) antibodies in Rh_o(D) negative females.

III. SAFETY PRECAUTIONS

A. Warnings:

1. HyperRHO®, is made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the CJD agent.
2. The risk that such products will transmit an infectious agent has been reduced by:
    a. Screening plasma donors for prior exposure to certain viruses.
    b. Testing for the presence of certain current virus infections.
    c. Inactivating and/or removing certain viruses during manufacturing.
3. Despite preventive measures, these products could still potentially transmit disease.
4. There is also the possibility that unknown infectious agents may be present in such products.
5. The physician should discuss the risks and benefits of this product with the patient.

B. Precautions:

1. For postpartum use, HyperRHO® is intended for maternal administration. It should not be given to the newborn infant.
2. The product is not intended for use in Rh_o(D)-positive individuals.
3. Rho(D) immune globulin (human) should be given with caution to patient with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. Such persons have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.
4. A large fetomaternal hemorrhage late in pregnancy or following delivery may cause a weak mixed field positive DU test result. If there is any doubt about the mother's Rh type, she should be given Rho(D) immune globulin (human). A fetal screen test to detect fetal red blood cells may be helpful in these cases.
5. If more than 15 mL of D-positive red blood cells are present in the mother's circulation, more than a single dose of HyperRHO® S/D Full Dose is required. Failure to recognize this may result in the administration of an inadequate dose.
6. Administration of live virus vaccines (e.g., MMR) should be deferred for approximately 3 months after administration
7. Parenteral drug products should be visually inspected for particulate matter. Do not use solutions that are cloudy or have deposits. It should be a pale yellow or pink solution.

C. Contraindications:
   1. The attending physician who wishes to administer HyperRHO to persons with isolate immunoglobulin A (IgA) deficiency must weigh the benefits of immunization against the potential for developing antibodies to IgA and could have anaphylactic reaction to subsequent administration of blood products that contain IgA.

D. Adverse Reactions:
   1. When anti-D immunoglobulins are administered by the intramuscular route, local pain and tenderness can be observed at the injection site; this can be prevented by dividing larger doses over several injection sites.
   2. Mild and transient fever, malaise, headache, cutaneous reactions and chills occur occasionally.
   3. Patients with incompatible transfusion who receive an overdose of anti-D immunoglobulin should be monitored clinically and by biological parameters because of the risk of hemolytic reaction.
   4. In other Rho(D)-negative individuals overdosage should not lead to more frequent or more severe undesirable effects than the normal dose.

IV. SPECIMEN

A. K^2 EDTA pink top tube
B. Store specimens at 1-10°C.
C. Hemolysis is unacceptable.

V. PROCEDURE

A. Indications and Usage:

1. Pregnancy and Obstetrical Conditions:
   a. HyperRHO® S/D Full Dose is recommended for:
      1) Suppression of Rh isoimmunization in non-sensitized Rh_o(D)-negative (D-negative) women.
      2) The criteria for a Rh-incompatible pregnancy requiring administration of Rhophylac® at 28 to 30 weeks of gestation and within 72 hours after delivery are:
         a) Mother must be Rh_o(D)-negative at immediate spin. Weak D testing does not need to be performed unless there is a positive fetal screen.
         b) Mother is carrying a child whose father is either Rh_o(D)-positive or Rh_o(D) unknown.
         c) Baby is either Rh_o(D)-positive or Rh_o(D) unknown.
         d) Mother must not be previously sensitized to the Rh_o(D) factor.
      3) Rhesus prophylaxis in case of obstetric complications, e.g., miscarriage, abortion, threatened abortion, ectopic pregnancy or hydatidiform mole, transplacental hemorrhage resulting from antepartum hemorrhage.
      4) Rhesus prophylaxis in case of invasive procedures during pregnancy, e.g., amniocentesis, chorionic biopsy or obstetric manipulative procedures, e.g., external version, or abdominal trauma.

2. Dosage and Administration:

Indication	Dose (administer IM)
Pregnancy Routine antepartum prevention (at 28 to 30 weeks of gestation)	**1500 IU (300 µg)**
*Postpartum prevention -within 72 hrs	**1500 IU (300 µg)**
Obstetric conditions Obstetric complications, e.g., miscarriage, abortion, threatened abortion, ectopic pregnancy or hydatidiform mole, transplacental hemorrhage resulting from	**1500 IU (300 µg)**

antepartum hemorrhage.	
Invasive procedures during pregnancy, e.g., amniocentesis, chorionic biopsy or obstetric manipulative procedures, e.g., external version, or abdominal trauma	**1500 IU (300 µg) at 13-18 weeks** Another dose should be given at 26-28 weeks to maintain protection.

*In case of known or suspected excessive fetomaternal hemorrhage, the number of fetal red blood cells in the maternal circulation should be determined. If excess transplacental bleeding is measured by flow, extra anti-D immunoglobulin [100 IU (20 µg) for each 1 mL of fetal red blood cells] should be administered. If testing is not feasible and an excessive fetomaternal hemorrhage cannot be excluded, a further 1500 IU (300 µg) should be administered. A 1500 IU (300 µg) dose will suppress the immunizing potential of at least 15 mL of Rh_o(D) positive red blood cells (1). HyperRHO® Rh_o(D) should be administered by intramuscular injection as soon as possible within 72 hours of delivery.

3. Protocol:
   a. Antepartum (28 weeks) (ANTRHG):
      1) The mother must be Rh_o(D) negative at immediate spin, no weak D testing is needed.
      2) The mother must not already be immunized to Rh_o(D). (Do an antibody screen.)
      3) The injection should be given within seven days of the date blood for antibody screen is drawn.
   b. Postpartum (Specimen collected ASAP after 1 hour post delivery.) Testing and injection will be performed at the hospital patient is transferred to.
   c. Miscarriage or threatened abortion (ANTRHG):
      1) Mother must be Rh_o(D) negative at immediate spin, no weak D testing is needed.
      2) The mother must not already be immunized to Rh_o(D). (Do an antibody screen.)
      3) If miscarriage or threatened abortion occurs at > 13 weeks, fetal screen is required. The Fetal Screen testing will be sent to UPH-Methodist (LAB896). A single dose of HyperRHO S/D Full Dose is to be given ASAP, and the patient called back in for any additional doses if necessary according to the Fetal Screen and the Fetal Hgb Determination for fetomaternal hemorrhage results.
      4) The injection(s) should be given within three days of event.
   d. HyperRHO S/D Full Dose may be used to prevent isoimmunization in Rho(D) negative individuals who have been transfused with Rho(D)

positive red blood cells or blood components containing red blood cells. Flow and pathology consultation needed for dosing.

VI. INTERPRETATION AND RESULTS

A. Result Reporting:

1. Fill out top half of the injection form (see UPPK BB-0145.01 for example) which is included with the product.
2. Enter information in computer in SunQuest-Blood Order Processing. The Du Antigen testing on the antenatal Rhogam orders (ANTRHG) will be resulted by using Not Performed (5 key) for the reactions and Not Required (;NRQ) for the Interpretation. Click on the allocation tab. Then click on the green Inventory Search button. Inventory information for our Rhogams will automatically fill in. Click on the search button to pull up all of the Rhogams in our inventory. Choose one with the earliest expiration date. Click Save and the Rhogam will be allocated to that patient.
3. Call the ER or PSC if the patient is waiting, to let them know the Rhogam injection is ready.

B. Picking up product:

1. Outpatients: Need a copy of the order prior to signing out.
2. Verify verbally from the computer (Blood Product Issue) with the person taking the product checking the completed Rhogam injection form for:
   a. Patient name
   b. Patient medical record number
   c. ABO and Rh type of patient
   d. Lot number of Rhogam
   *Then repeat the verbal verification with the person picking up reading out loud while we are checking the same information as above.
3. Document in computer (BPI):
   a. Visual inspection of the product (pass or fail)
   b. Date and time product issued
   c. First initial and entire last name of person taking product
   *Click SAVE at the bottom of the screen after all information is entered.
4. Person giving injection must complete bottom half of injection form, place top copy in patient chart and return remaining two copies to Blood Bank.

VII. REFERENCES

A. Grifols Therapeutics Inc., Research Triangle Park NC 27709, US license No. 1871, 3047929 (Rev.02/2018).
B. AABB Technical Manual, Nineteenth Edition, Bethesda, Maryland 20817, ISBN No. 978-1-56395-947-9, 2017.

POLICY CREATION :		Date
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SECTION MEDICAL DIRECTOR		

Reviewed by:

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date
01	UPH format and test codes	Jenny Turner	10/08/18
02	Sunquest instructions	Jenny Turner	11/03/18
03	If mother weak D positive, notify physician	Jenny Turner	12/06/18
04	Omitted weak D testing on females of childbearing age, added Du antigen will be automatically hidden on Rhogam orders in SQ, added weak D on positive fetal screens.	Jenny Turner	02/26/19
05	Added instructions for how to repeat out the Du in SQ not performed anymore, clerical error fixed	Jenny Turner	05/03/19
06	Deleted postpartum Rhogam testing. Added information on sending Fetal Screens to Methodist.	Jenny Turner	8/27/19

Lead	Date	Coordinator/ Manager	Date	Medical Director	Date