HYPERRHO S/D MINI-DOSE - human rho(d) immune globulin solution
Grifols Therapeutics Inc.

DESCRIPTION

Rh_o(D) Immune Globulin (Human) — Hyper**RHO**® S/D Mini-Dose treated with solvent/ detergent is a colorless to pale yellow or pink sterile solution of immune globulin containing antibodies to Rh_o(D) for intramuscular administration; it is preservative-free, in a latex-free delivery system. Hyper**RHO** S/D Mini-Dose is prepared by cold ethanol fractionation from human plasma. The immune globulin is isolated from solubilized Cohn Fraction II. The Fraction II solution is adjusted to a final concentration of 0.3% tri-n-butyl phosphate (TNBP) and 0.2% sodium cholate. After the addition of solvent (TNBP) and detergent (sodium cholate), the solution is heated to 30°C and maintained at that temperature for not less than 6 hours. After the viral inactivation step, the reactants are removed by precipitation, filtration and finally ultrafiltration and diafiltration. Hyper**RHO** S/D Mini-Dose is then incubated in the final container for 21–28 days at 20–27°C. Hyper**RHO** S/D Mini-Dose is formulated as a 15–18% protein solution at a pH of 6.4–7.2 in 0.21–0.32 M glycine. One dose of Hyper**RHO** S/D Mini-Dose contains not less than one-sixth the quantity of Rh_o(D) antibody contained in one standard dose of Rh_o(D) Immune Globulin (Human), and it will suppress the immunizing potential of 2.5 mL of Rh_o(D) positive packed red blood cells or the equivalent of whole blood (5 mL). The quantity of Rh_o(D) antibody in Hyper**RHO** S/D Mini-Dose is not less than 250 IU.

The removal and inactivation of spiked model enveloped and non-enveloped viruses during the manufacturing process for Hyper**RHO** S/D Mini-Dose has been validated in laboratory studies. Human Immunodeficiency Virus, Type 1 (HIV-1), was chosen as the relevant virus for blood products; Bovine Viral Diarrhea Virus (BVDV) was chosen to model Hepatitis C virus; Pseudorabies virus (PRV) was chosen to model Human Herpes viruses and other large enveloped DNA viruses; and Reo virus type 3 (Reo) was chosen to model non-enveloped viruses and for its resistance to physical and chemical inactivation. Significant removal of model enveloped and non-enveloped viruses is achieved at two steps in the Cohn fractionation process leading to the collection of Cohn Fraction II: the precipitation and removal of Fraction III in the processing of Fraction II + IIIW suspension to Effluent III and the filtration step in the processing of Effluent III to Filtrate III. Significant inactivation of enveloped viruses is achieved at the time of treatment of solubilized Cohn Fraction II with TNBP/sodium cholate.

Additionally, the manufacturing process was investigated for its capacity to decrease the infectivity of an experimental agent of transmissible spongiform encephalopathy (TSE), considered as a model for the vCJD and CJD agents. [11-14]

Studies of the Hyper**RHO** S/D manufacturing process demonstrate that TSE clearance is achieved during the Pooled Plasma to Effluent III Fractionation Process (6.7 $\log_{10}$). These studies provide reasonable assurance that low levels of CJD/vCJD agent infectivity, if present in the starting material, would be removed.

CLINICAL PHARMACOLOGY

Rh sensitization may occur in nonsensitized Rh_o(D) negative women following transplacental hemorrhage resulting from spontaneous or induced abortions. [1-2] The risk of sensitization is higher in women undergoing induced abortions than in those aborting spontaneously. [1-3]

Hyper**RHO** S/D Mini-Dose is used to prevent the formation of anti-Rh_o(D) antibody in Rh_o(D) negative women who are exposed to the Rh_o(D) antigen at the time of spontaneous or induced abortion (up to 12 weeks' gestation). [3-5] Hyper**RHO** S/D Mini-Dose suppresses the stimulation of active immunity by Rh_o(D) positive fetal erythrocytes that may enter the maternal circulation at the time of termination of the pregnancy.

The amount of anti-Rh_o(D) in Hyper**RHO** S/D Mini-Dose has been shown to effectively prevent maternal isosensitization to the Rh_o(D) antigens following spontaneous or induced abortion occurring up to the 12th week of gestation. [6-8] After the 12th week of gestation, a standard dose of Hyper**RHO** S/D Full Dose is indicated.

In a clinical study in eight healthy human adults receiving another hyperimmune immune globulin product treated with solvent/ detergent, Rabies Immune Globulin (Human), Hyper**RAB**® S/D, prepared by the same manufacturing process, detectable passive antibody titers were observed in the serum of all subjects by 24 hours post injection and persisted through the 21 day study period. These results suggest that passive immunization with immune globulin products is not affected by the solvent/detergent treatment.

INDICATIONS AND USAGE

Hyper**RHO** S/D Mini-Dose is recommended to prevent the isoimmunization of Rh_o(D) negative women at the time of spontaneous or induced abortion of up to 12 weeks' gestation provided the following criteria are met:

1. The mother must be Rh_o(D) negative and must not already be sensitized to the Rh_o(D) antigen.

2. The father is not known to be Rh_o(D) negative.

3. Gestation is not more than 12 weeks at termination.

Note: Rh_o(D) Immune Globulin (Human) prophylaxis is not indicated if the fetus or father can be determined to be Rh negative. If the Rh status of the fetus is unknown, the fetus must be assumed to be Rh_o(D) positive, and Hyper**RHO** S/D Mini-Dose should be administered to the mother.
FOR ABORTIONS OR MISCARRIAGES OCCURRING AFTER 12 WEEKS' GESTATION, A STANDARD DOSE OF Rh_o(D) IMMUNE GLOBULIN (HUMAN) IS INDICATED.
Hyper**RHO** S/D Mini-Dose should be administered within 3 hours or as soon as possible after spontaneous passage or surgical removal of the products of conception. However, if Hyper**RHO** S/D Mini-Dose is not given within this time period, consideration should still be given to its administration since clinical studies in male volunteers have demonstrated the effectiveness of Rh_o(D) Immune Globulin (Human) in preventing isoimmunization as long as 72 hours after infusion of Rh_o(D) positive red cells. [9]

CONTRAINDICATIONS
None known.

WARNINGS
HyperRHO S/D Mini-Dose is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt-Jakob Disease (CJD) agent that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/ or symptoms of some viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Therapeutics Inc. [1-800-520-2807].
The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient.
NEVER ADMINISTER HYPER**RHO** S/D MINI-DOSE INTRAVENOUSLY. INJECT ONLY INTRAMUSCULARLY. ADMINISTER ONLY TO WOMEN POSTABORTION OR POSTMISCARRIAGE OF UP TO 12 WEEKS' GESTATION. NEVER ADMINISTER TO THE NEONATE.
Hyper**RHO** S/D Mini-Dose should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations.
The attending physician who wishes to administer Hyper**RHO** S/D Mini-Dose to persons with isolated immunoglobulin A (IgA) deficiency must weigh the benefits of immunization against the potential risks of hypersensitivity reactions. Such persons have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.
As with all preparations administered by the intramuscular route, bleeding complications may be encountered in patients with thrombocytopenia or other bleeding disorders.

PRECAUTIONS

General
Although systemic reactions to immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactic symptoms.

Drug Interactions
Other antibodies in the Hyper**RHO** S/D Mini-Dose preparation may interfere with the response to live vaccines such as measles, mumps, polio or rubella. Therefore, immunization with live vaccines should not be given within 3 months after Hyper**RHO** S/D Mini-Dose administration.

Pregnancy Category C
Animal reproduction studies have not been conducted with Hyper**RHO** S/D Mini-Dose. It is also not known whether Hyper**RHO** S/D Mini-Dose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.
It should be again noted, however, that Hyper**RHO** S/D Mini-Dose is **not** indicated for use during pregnancy and it should be administered only postabortion or postmiscarriage.

Pediatric Use
Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS

Reactions to Hyper**RHO** S/D Mini-Dose are infrequent in Rh_o(D) negative individuals and consist primarily of slight soreness at the site of injection and slight temperature elevation. While sensitization to repeated injections of human globulin is extremely rare, it has occurred.

DOSAGE AND ADMINISTRATION

NEVER ADMINISTER HYPER**RHO** S/D MINI-DOSE INTRAVENOUSLY. INJECT ONLY INTRAMUSCULARLY. ADMINISTER ONLY TO WOMEN POSTABORTION OR POSTMISCARRIAGE OF UP TO 12 WEEKS' GESTATION. NEVER ADMINISTER TO THE NEONATE.

One syringe of Hyper**RHO** S/D Mini-Dose provides sufficient antibody to prevent Rh sensitization to 2.5 mL Rh_o(D) positive packed red cells or the equivalent (5 mL) of whole blood. This dose is sufficient to provide protection against maternal Rh sensitization for women undergoing spontaneous or induced abortion of up to 12 weeks' gestation.

Rh_o(D) Immune Globulin (Human) — Hyper**RHO**® S/D Mini-Dose should be administered within 3 hours or as soon as possible following spontaneous or induced abortion. If prompt administration is not possible, Hyper**RHO** S/D Mini-Dose should be given within 72 hours following termination of the pregnancy.

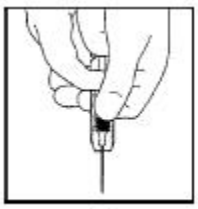
Hyper**RHO** S/D Mini-Dose is administered **intramuscularly,** preferably in the deltoid muscle of the upper arm or lateral thigh muscle. The gluteal region should not be used as an injection site because of the risk of injury to the sciatic nerve. [10]

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Hyper**RHO** S/D Mini-Dose is supplied with a syringe and an attached UltraSafe® Needle Guard for your protection and convenience. Please follow instructions below for proper use of syringe and UltraSafe® Needle Guard.

Directions for Syringe Usage

1. Remove the prefilled syringe from the package. Lift syringe by barrel, **not** by plunger.
2. Twist the plunger rod clockwise until the threads are seated.
3. With the rubber needle shield secured on the syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the rubber stopper and the glass syringe barrel.
4. Remove the needle shield and expel air bubbles. [Do not remove the rubber needle shield to prepare the product for administration until immediately prior to the anticipated injection time.]
5. Proceed with hypodermic needle puncture.
6. Aspirate prior to injection to confirm that the needle is not in a vein or artery.
7. Inject the medication.
8. Keeping your hands behind the needle, grasp the guard with free hand and slide forward toward needle until it is completely covered and guard clicks into place. If audible click is not heard, guard may not be completely activated. (See Diagrams A and B)
9. Place entire prefilled glass syringe with guard activated into an approved sharps container for proper disposal. (See Diagram C)


A

B

C

A number of factors could reduce the efficacy of this product or even result in an ill effect following its use. These include improper storage and handling of the product after it leaves our hands, diagnosis, dosage, method of administration, and biological differences in individual patients. Because of these factors, it is important that this product be stored properly and that the directions be followed carefully during use.

HOW SUPPLIED

Hyper**RHO** S/D Mini-Dose package contains 10 single dose syringes. Hyper**RHO** S/D Mini-Dose is preservative-free, in a latex-free delivery system.

NDC Number	Size

13533-661-06 Syringe (10 pack)

STORAGE
Store at 2–8°C (36–46°F). Do not freeze.

CAUTION
Rx only
U.S. federal law prohibits dispensing without prescription.

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The Rh Factor and Your Pregnancy

Information About Pregnancy Protection

The Rh Factor and When It Is Important

The Rh factor is one of many blood group antigens found on the surface of red blood cells. If you have this antigen you are considered Rh positive. If you don't, then you are considered Rh negative. Everyone is either Rh positive or Rh negative. One type is neither better nor worse than the other, only different.

Your Rh factor is important if you are an Rh negative woman and you become pregnant, or if you receive a blood transfusion.

How the Rh Factor Can Affect Your Future

If you have Rh negative blood, there are two situations that can affect you:

1. If the father of your baby is Rh positive, the baby will probably be Rh positive too. An Rh negative woman carrying an Rh positive baby may have an immune reaction if some of the baby's Rh positive blood cells enter her bloodstream.

   This immune reaction, called isoimmunization, means your body's defense system recognizes Rh positive blood as foreign from your own and produces "antibodies" to destroy the invading Rh positive blood cells.

   The passage of blood from the baby to the mother's bloodstream happens most often at delivery, but can also occur during miscarriage, the termination of pregnancy, amniocentesis (test performed to determine fetal health), or due to an injury or trauma. It is important to note that a small number of women develop antibodies to Rh positive blood cells during pregnancy for no apparent reason.

   Antibodies to Rh positive blood may not be a problem in first pregnancies; however, the antibodies stay in your bloodstream, ready to attack invading Rh positive blood cells, for many years to come. This can lead to problems in future pregnancies by causing miscarriage or a disease known as hemolytic disease of the newborn.

   Babies born to Rh positive mothers, regardless of the father's blood type, will usually be free of the dangers of hemolytic disease.

2. Someday it may become necessary for you to receive a blood transfusion. If Rh positive antibodies already reside in your bloodstream due to isoimmunization and the blood you receive is Rh positive due to error or lifesaving reasons, your Rh positive antibodies will become mobilized and destroy the donor Rh positive cells. As a result, the transfusion could be unsuccessful and possibly harmful to you.

Hemolytic Disease of the Newborn: A Threat to Your Baby

When an Rh negative woman has Rh positive antibodies in her blood and the baby she is carrying is Rh positive, the antibodies could possibly enter the baby's bloodstream, attack the baby's red blood cells and cause hemolytic disease of the newborn. At birth, the infant suffering from hemolytic disease may be jaundiced and anemic or suffer permanent damage of the brain and central nervous system which may result in mental retardation, hearing loss, or cerebral palsy. Extensive medical care can be required, including an exchange transfusion, in which all of the baby's blood is replaced. This usually stops the destruction of the baby's red blood cells and gives the infant a chance to survive.

The risk of hemolytic disease of the newborn is slight with the first baby, but increases with each successive pregnancy.

Preventing Hemolytic Disease

Hyper**RHO**® S/D, Rh_o(D) Immune Globulin (Human) can prevent hemolytic disease of the newborn, provided Rh positive antibodies do not already reside in your bloodstream.

Hyper**RHO** S/D is a specially prepared gamma globulin with a high level of preformed antibodies against Rh positive blood cells. The injection of Hyper**RHO** S/D destroys any Rh positive blood cells that may have entered the mother's bloodstream and prevents the mother's immune system from producing Rh positive antibodies; thus protecting the baby from developing hemolytic disease.

HyperRHO S/D Full Dose — When Prescribed

Pregnancy and Other Obstetric Conditions Pertaining to Rh Negative Women

Hyper**RHO** S/D Full Dose is administered during pregnancy if you fall into a high-risk category. For example, you are at risk of producing Rh positive antibodies if you have an amniocentesis procedure performed, or if you have a miscarriage or other termination of pregnancy at or beyond 13 weeks' gestation.

Laboratory findings have shown that some Rh negative women develop Rh positive antibodies during the last weeks of pregnancy even without an antibody-stimulating event. As a preventive measure, your physician will probably recommend the first injection of Hyper**RHO** S/D Full Dose at the 28th week of pregnancy.

In both of the above situations, if the blood type of the father or baby can be determined to be Rh negative, an injection of Hyper**RHO** S/D is not required.

Another injection of Hyper**RHO** S/D Full Dose is administered within 72 hours of delivery of an Rh positive baby.

Blood Transfusion

Hyper**RHO** S/D Full Dose may be used to prevent isoimmunization in Rh negative individuals who have been transfused with Rh positive red blood cells or blood components containing red blood cells.

HyperRHO S/D Mini-Dose — When Prescribed

A single dose of Hyper**RHO** S/D Mini-Dose may be prescribed for an Rh negative woman instead of Hyper**RHO** S/D Full Dose in the event of miscarriage or other termination of pregnancy occurring **prior** to 13 weeks' gestation. Hyper**RHO** S/D Mini-Dose is not required if the blood type of the father or fetus can be determined to be Rh negative.

Will You Need HyperRHO S/D Again?

Hyper**RHO** S/D provides protection only if you have not already produced Rh positive antibodies. Women who have developed antibodies through previous pregnancy, miscarriage, other termination of pregnancy, or blood transfusion cannot be protected by Hyper**RHO** S/D. This is why with each pregnancy it is important to have Hyper**RHO** S/D injections within the prescribed time period.

Reactions to HyperRHO S/D

You may feel a temporary soreness at the site of the injection. You may also have a slight and temporary change in body temperature. In very rare instances, an allergic type of reaction can occur, for which your physician will take appropriate measures.

Delivering a Sound, Healthy Baby

Your physician can answer any questions you may have about receiving a Hyper**RHO** S/D injection to prevent hemolytic disease of the newborn. If you know that you are Rh negative and you are pregnant, you should discuss your situation with your physician. Today, with Hyper**RHO** S/D, hemolytic disease of the newborn can be reduced to its lowest possible rate of incidence.

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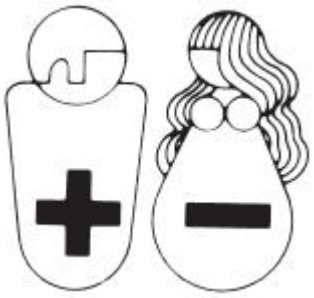
Development of Hemolytic Disease

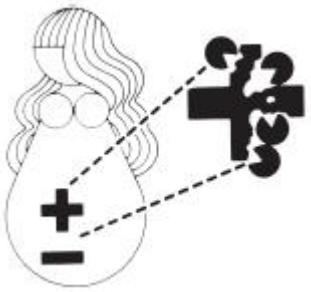
1
Rh positive (+) father.
Rh negative (–) mother.



2
Pregnancy: Rh– mother is carrying Rh+ baby.

3
The passage of Rh+ blood from the baby to the mother's bloodstream happens most often at delivery, but can also occur during miscarriage, other termination of pregnancy, amniocentesis, or due to injury or trauma.

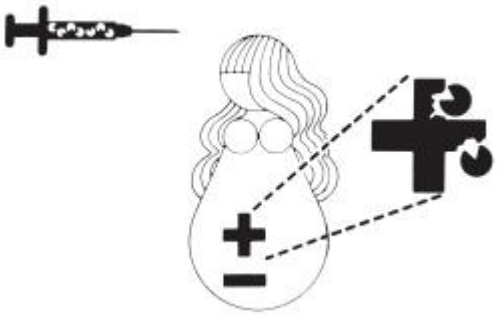
4
Rh+ antibodies stay in your bloodstream, ready to attack invading Rh+ blood cells, for many years to come.



5
Next pregnancy, mother’s Rh+ antibodies enter baby’s Rh+ bloodstream,
attacking baby’s blood cells and causing hemolytic disease of the newborn.

How HyperRHO S/D Immune Globulin Can Prevent Hemolytic Disease

1
You will probably be given two injections of Hyper**RHO** S/D Full Dose, one at the 28th week of your pregnancy and another within 72 hours of delivery, miscarriage or other termination of pregnancy. A single injection of Hyper**RHO** S/D Mini-Dose may be prescribed instead of Hyper**RHO** S/D Full Dose in the event of miscarriage or other termination of pregnancy occurring prior to 13 weeks' gestation.



2
Hyper**RHO** S/D immunization prevents formation of mother’s own Rh+ antibodies. Mother’s bloodstream remains free of Rh+ antibodies.

3
Next pregnancy, baby develops normally. Hyper**RHO** S/D should be administered following delivery, miscarriage, or other termination of pregnancy to continue protection if baby is Rh+.

PACKAGE LABEL
Rh_o(D)Immune Globulin (Human)

HyperRHO® S/D Mini-Dose
Solvent/Detergent Treated
Preservative-free, latex-free delivery system
Contents: 10 single dose disposable syringes with attached needles
The patient and physician should discuss the risks and benefits of this product.

Rh_o(D) Immune Globulin (Human) — Hyper**RHO**® S/D Mini-Dose is a sterile solution of immunoglobulin containing 15%–18% protein stabilized with 0.21–0.32 M glycine. The pH is adjusted with sodium carbonate.

The quantity of Rh_o(D) antibody in each single dose syringe of Hype**rRHO**® S/D Mini-Dose is not less than 250 IU. One dose will suppress the immunizing potential of 2.5 mL Rh_o(D) positive packed red cells or the equivalent of whole blood (5.0 mL).

FOR INTRAMUSCULAR INJECTION ONLY. DO NOT GIVE INTRAVENOUSLY. NEVER ADMINISTER TO NEONATES.
Store at 2–8°C (36–46°F). Do not freeze.
For complete dosage and administration information, read enclosed package insert.
For directions for syringe usage, see enclosed package insert.
Do not use if the syringe is prematurely engaged.
Not returnable for credit or exchange.
Rx only
CAUTION: U.S. federal law prohibits dispensing without prescription.
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