Rh(D) Immune Globulin (Human)

HyperRHO® S/D Full Dose

S中方入Tentant

Rh(D) Immune Globulin (Human) — HyperRHO® S/D Full Dose is infused with saline or bacteriostatic water (0.9% sodium chloride) or sterile water for injection and is not intended for intravenous use. It is administered intramuscularly and intravenously.

CLINICAL PHARMACOLOGY

HyperRHO® S/D is a product intended to prevent isoimmunization in the Rh (D) negative mother. It is derived from the human plasma of donors who are Rh (D) positive. The preparation is administered as a solution of immune globulin. The preparation contains no Rh positive antibodies. Women who have developed Rh positive antibodies through previous pregnancy and have a subsequent pregnancy with an Rh positive baby should receive Rh immune globulin to prevent Rh incompatibility. This product contains no human plasma components that may cause anaphylaxis, anaphylactoid reaction, or other allergic reactions.

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 not better than the other; they are just different.

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

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

1. 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 not have antibodies to the Rh positive fetal red blood cells. Therefore, if some of the baby’s Rh positive fetal blood cells enter her bloodstream this immune reaction can cause problems. If you are Rh negative, this means that you do not have the Rh positive protein on your red blood cells. You have no Rh positive blood and cannot form Rh positive antibodies.

2. You may develop antibodies if you receive a blood transfusion. Rh positive antibodies already reside in your bloodstream that react with Rh negative red blood cells. This occurs because you have been exposed to Rh positive red blood cells. Anaemia, Rh factor, and Your Pregnancy

The Rh Factor

The Rh Factor

S/D Full Dose is formulated as a 15–18% protein solution at a pH of 6.4–7.2 in 0.21–0.32 M NaCl. HyperRHO® S/D Full Dose is sterile and pyrogen-free and is intended for single dose use.

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Pregnancy Category C

Antibody formation does not have to be completely eliminated by the time of delivery. Complete elimination may not be possible. The half-life of maternal IgG antibodies is 23-26 days. After a single injection of Hyper Rho negative (–) mother. Rh positive (+) father.

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.

Pregnancy: Rh– mother is carrying Rh+ baby.

Development of S/D Immune Globulin RHO

1. Remove the prefilled syringe from the package. Lift syringe by barrel, 
Directions for Syringe Usage

8. Keeping your hands behind the needle, grasp the guard with free hand and slide 
7. Inject the medication. 
4. Remove the needle shield and expel air bubbles. Do not remove the rubber needle 
of the risk of injury to the sciatic nerve. (17)

administered within 72 hours after an incompatible transfusion, but preferably as soon as 
If abdominal trauma, amniocentesis, or other adverse event requires the administration of 

ADVERSE REACTIONS

Pediatric Use

some individuals receiving multiple doses of Rho(D) Immune Globulin (Human) following 

REFERENCES

13. Prevention of Rh sensitization.


U.S. License No. 1871 (Rev. 10/2014)

3. Following threatened abortion at any stage of gestation with continuation of pregnancy,

2. For antenatal prophylaxis, one full dose syringe of Hyper 

1. Calculate the number of syringes of Hyper 

NEVER ADMINISTER HYPEROglobulin (Human) — Hyper 


INTRAMUSCULARLY. NEVER ADMINISTER TO THE NEONATE.

Hypersensitivity reactions and anaphylactic shock have been reported with the use of this product.

The use of this product does not ensure that the baby will not have Rh+ blood or Rh+ red cells in the mother's blood at some time in the future, and the occurrence of immunization cannot be precluded. Therefore, this product should be used in all Rh– women who are carrying Rh+ babies. A single dose may be sufficient for the prevention of Rh immunization.

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3.2-3 mL of Rh+ red cells) should be performed to determine 

S/D Full Dose is supplied with a syringe and an attached UltraSafe® Needle 

GRIFOLS

Griﬃths Therapeutics Inc.
2500 Connecticut Ave, N.W.
Washington, D.C. 20008 USA
(Rev. 12/2014)

S/D Full Dose is packaged as 1 syringe per carton, and as 10 syringes per 

A number of factors could reduce the efficacy of this product or even result in an ill effect 

Boxed Warning

Instruct patient that the needle should not be reused.

A second or subsequent dose of Hyper 

S/D Full Dose provides sufficient antibody to prevent Rh sensitization if the 

If more than one syringe is required, divide the total number of 

Paternal drug products should be expected reality for particular mother and disclosa-

INJECT ENTIRE CONTENTS OF THE SYRINGE INTO THE INDIVIDUAL INTRAMUS-

S/D Full Dose to be given as described under Dosage in the Dosage section. 

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