

Rh₀(D) Immune Globulin (Human)

BayRho-D[®] Full Dose

Solvent/Detergent Treated

DESCRIPTION

Rh₀(D) Immune Globulin (Human) — BayRho-D[®] Full Dose treated with solvent/detergent is a sterile solution of immune globulin containing antibodies to Rh₀(D) for intramuscular administration; it contains no preservative. BayRho-D Full 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. BayRho-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 glycine. BayRho-D Full Dose is then incubated in the final container for 21–28 days at 20–27°C.

The potency is equal to or greater than that of the U.S. Food and Drug Administration Reference Rh₀(D) Immune Globulin. Each single dose vial or syringe contains sufficient anti-Rh₀(D) (approximately 300 µg*) to effectively suppress the immunizing potential of 15 mL of Rh₀(D) positive red blood cells.²⁻⁴

The removal and inactivation of spiked model enveloped and non-enveloped viruses during the manufacturing process for BayRho-D Full 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 Hepatitis B virus and the Herpes 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.

*A full dose of Rh₀(D) Immune Globulin (Human) has traditionally been referred to as a “300 µg” dose and this usage is employed here for convenience in terminology. It should not be construed as the actual anti-D content. Each full dose of Rh₀(D) Immune Globulin (Human) must contain at least as much anti-D as 1 mL of the U.S. Reference Rh₀(D) Immune Globulin. Studies performed at the FDA have shown that the U.S. Reference contains 820 international units (IU) of anti-D per mL. When the conversion factor determined for the International (WHO) Reference Preparation¹ is used, 820 IU per mL is equivalent to 164 µg per mL of anti-D.

CLINICAL PHARMACOLOGY

BayRho-D Full Dose is used to prevent isoimmunization in the Rh₀(D) negative individual exposed to Rh₀(D) positive blood as a result of a fetomaternal hemorrhage occurring during a delivery of an Rh₀(D) positive infant, abortion (either spontaneous or induced), or following amniocentesis or abdominal trauma. Similarly, immunization resulting in the production of anti-Rh₀(D) following transfusion of Rh positive red cells to an Rh₀(D) negative recipient may be prevented by administering Rh₀(D) Immune Globulin (Human).^{5,6}

Rh hemolytic disease of the newborn is the result of the active immunization of an Rh₀(D) negative mother by Rh₀(D) positive red cells entering the maternal circulation during a previous delivery, abortion, amniocentesis, abdominal trauma, or as a result of red cell transfusion.^{7,8} BayRho-D Full Dose acts by suppressing the immune response of Rh₀(D) negative individuals to Rh₀(D) positive red blood cells. The mechanism of action of BayRho-D Full Dose is not fully understood.

The administration of Rh_o(D) Immune Globulin (Human) within 72 hours of a full-term delivery of an Rh_o(D) positive infant by an Rh_o(D) negative mother reduces the incidence of Rh isoimmunization from 12%–13% to 1%–2%.⁹

The 1%–2% treatment failures are probably due to isoimmunization occurring during the latter part of pregnancy or following delivery.¹⁰ Bowman and Pollock¹¹ have reported that the incidence of isoimmunization can be further reduced from approximately 1.6% to less than 0.1% by administering Rh_o(D) Immune Globulin (Human) in two doses, one antenatal at 28 weeks' gestation and another following delivery.

In a clinical study in eight healthy human adults receiving another hyperimmune immune globulin product treated with solvent/detergent, Rabies Immune Globulin (Human), BayRab®, 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

Pregnancy and Other Obstetric Conditions

BayRho-D Full Dose is recommended for the prevention of Rh hemolytic disease of the newborn by its administration to the Rh_o(D) negative mother within 72 hours after birth of an Rh_o(D) positive infant,¹² providing 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) factor.
2. Her child must be Rh_o(D) positive, and should have a negative direct antiglobulin test (see PRECAUTIONS).

If BayRho-D Full Dose is administered antepartum, it is essential that the mother receive another dose of BayRho-D Full Dose after delivery of an Rh_o(D) positive infant.

If the father can be determined to be Rh_o(D) negative, BayRho-D Full Dose need not be given.

BayRho-D Full Dose should be administered within 72 hours to all nonimmunized Rh_o(D) negative women who have undergone spontaneous or induced abortion, following ruptured tubal pregnancy, amniocentesis or abdominal trauma unless the blood group of the fetus or the father is known to be Rh_o(D) negative.^{7,8} If the fetal blood group cannot be determined, one must assume that it is Rh_o(D) positive,² and BayRho-D Full Dose should be administered to the mother.

Transfusion

BayRho-D Full Dose may be used to prevent isoimmunization in Rh_o(D) negative individuals who have been transfused with Rh_o(D) positive red blood cells or blood components containing red blood cells.^{5,13}

CONTRAINDICATIONS

None known.

WARNINGS

BayRho-D Full Dose is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, 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 Bayer Corporation [1-888-765-3203].

The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient.

NEVER ADMINISTER BAYRHO-D FULL DOSE INTRAVENOUSLY. INJECT ONLY INTRAMUSCULARLY. NEVER ADMINISTER TO THE NEONATE.

Rh_o(D) Immune Globulin (Human) should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.

The attending physician who wishes to administer Rh_o(D) Immune Globulin (Human) 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

A large fetomaternal hemorrhage late in pregnancy or following delivery may cause a weak mixed field positive D^u test result. If there is any doubt about the mother's Rh type, she should be given Rh_o(D) Immune Globulin (Human). A screening test to detect fetal red blood cells may be helpful in such cases.

If more than 15 mL of D-positive fetal red blood cells are present in the mother's circulation, more than a single dose of BayRho-D Full Dose is required. Failure to recognize this may result in the administration of an inadequate dose.

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

Drug Interactions

Other antibodies in the Rh_o(D) Immune Globulin (Human) 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 Rh_o(D) Immune Globulin (Human) administration.

Drug/Laboratory Interactions

Babies born of women given Rh_o(D) Immune Globulin (Human) antepartum may have a weakly positive direct antiglobulin test at birth.

Passively acquired anti-Rh_o(D) may be detected in maternal serum if antibody screening tests are performed subsequent to antepartum or postpartum administration of Rh_o(D) Immune Globulin (Human).

Pregnancy Category C

Animal reproduction studies have not been conducted with BayRho-D Full Dose. It is also not known whether BayRho-D Full Dose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. BayRho-D Full Dose should be given to a pregnant woman only if clearly needed.

Pediatric Use

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

ADVERSE REACTIONS

Reactions to Rh_o(D) Immune Globulin (Human) 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 immune globulin is extremely rare, it has occurred. Elevated bilirubin levels have been reported in some individuals receiving multiple doses of Rh_o(D) Immune Globulin (Human) following mismatched transfusions. This is believed to be due to a relatively rapid rate of foreign red cell destruction.

DOSAGE AND ADMINISTRATION

NEVER ADMINISTER RH₀(D) IMMUNE GLOBULIN (HUMAN) — BAYRHO-D® FULL DOSE INTRAVENOUSLY. INJECT ONLY INTRAMUSCULARLY. NEVER ADMINISTER TO THE NEONATE.

Pregnancy and Other Obstetric Conditions

1. For postpartum prophylaxis, administer one vial or syringe of BayRho-D Full Dose (300 µg*), preferably within 72 hours of delivery. Although a lesser degree of protection is afforded if Rh antibody is administered beyond the 72-hour period, BayRho-D Full Dose may still be given.^{7,14} Full-term deliveries can vary in their dosage requirements depending on the magnitude of the fetomaternal hemorrhage. One 300 µg* vial or syringe of BayRho-D Full Dose provides sufficient antibody to prevent Rh sensitization if the volume of red blood cells that has entered the circulation is 15 mL or less.²⁻⁴ In instances where a large (greater than 30 mL of whole blood or 15 mL red blood cells) fetomaternal hemorrhage is suspected, a fetal red cell count by an approved laboratory technique (e.g., modified Kleihauer-Betke acid elution stain technique) should be performed to determine the dosage of immune globulin required.^{8,15} The red blood cell volume of the calculated fetomaternal hemorrhage is divided by 15 mL to obtain the number of vials or syringes of BayRho-D Full Dose for administration.^{3,8,13} If more than 15 mL of red cells is suspected or if the dose calculation results in a fraction, administer the next higher whole number of vials or syringes (e.g., if 1.4, give 2 vials or 2 syringes).
2. For antenatal prophylaxis, one 300 µg* vial or syringe of BayRho-D Full Dose is administered at approximately 28 weeks' gestation. This **must** be followed by another 300 µg* dose, preferably within 72 hours following delivery, if the infant is Rh positive.
3. Following threatened abortion at any stage of gestation with continuation of pregnancy, it is recommended that 300 µg* of BayRho-D Full Dose be given. If more than 15 mL of red cells is suspected due to fetomaternal hemorrhage, the same dose modification in No. 1 above applies.
4. Following miscarriage, abortion, or termination of ectopic pregnancy at or beyond 13 weeks' gestation, it is recommended that 300 µg* of BayRho-D Full Dose be given. If more than 15 mL of red cells is suspected due to fetomaternal hemorrhage, the same dose modification in No. 1 above applies. If pregnancy is terminated prior to 13 weeks' gestation, where licensed, a single dose of BayRho-D® Mini-Dose (approximately 50 µg*) may be used instead of BayRho-D Full Dose.
5. Following amniocentesis at either 15 to 18 weeks' gestation or during the third trimester, or following abdominal trauma in the second or third trimester, it is recommended that 300 µg* of BayRho-D Full Dose be administered. If there is a fetomaternal hemorrhage in excess of 15 mL of red cells, the same dose modification in No. 1 applies.

If abdominal trauma, amniocentesis, or other adverse event requires the administration of BayRho-D Full Dose at 13 to 18 weeks' gestation, another 300 µg* dose should be given at 26 to 28 weeks. To maintain protection throughout pregnancy, the level of passively acquired anti-Rh₀(D) should not be allowed to fall below the level required to prevent an immune response to Rh positive red cells. The half-life of IgG is 23 to 26 days. In any case, a dose of BayRho-D Full Dose should be given within 72 hours after delivery if the baby is Rh positive. If delivery occurs within 3 weeks after the last dose, the postpartum dose may be withheld unless there is a fetomaternal hemorrhage in excess of 15 mL of red blood cells.¹⁶

* See footnote under DESCRIPTION.

Transfusion

In the case of a transfusion of Rh₀(D) positive red cells to an Rh₀(D) negative recipient, the volume of Rh positive whole blood administered is multiplied by the hematocrit of the donor unit giving the volume of red blood cells transfused. The volume of red blood cells is divided by 15 mL which provides the number of vials or syringes of BayRho-D Full Dose to be administered.

If the dose calculated results in a fraction, the next higher whole number of vials or syringes should be administered (e.g., if 1.4, give 2 vials or 2 syringes). BayRho-D Full Dose should be administered within 72 hours after an incompatible transfusion, but preferably as soon as possible.

Injection Procedure

DO NOT INJECT INTRAVENOUSLY. DO NOT INJECT NEONATE. BayRho-D Full Dose is administered **intramuscularly**, preferably in the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. The gluteal region should not be used routinely as an injection site because of the risk of injury to the sciatic nerve. If the gluteal region is used, the central region **MUST** be avoided; only the upper, outer quadrant should be used.¹⁷

A. Single Vial or Syringe Dose

INJECT ENTIRE CONTENTS OF THE VIAL OR SYRINGE INTO THE INDIVIDUAL INTRAMUSCULARLY.

B. Multiple Vial or Syringe Dose

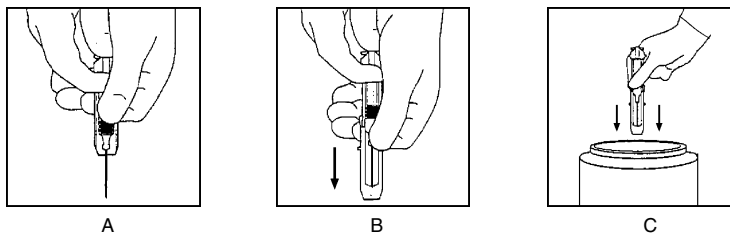
1. Calculate the number of vials or syringes of BayRho-D Full Dose to be given (see Dosage section).
2. The total volume of BayRho-D Full Dose can be given in divided doses at different sites at one time or the total dose may be divided and injected at intervals, provided the total dosage is given within 72 hours of the fetomaternal hemorrhage or transfusion. USING STERILE TECHNIQUE, INJECT THE ENTIRE CONTENTS OF THE CALCULATED NUMBER OF VIALS OR SYRINGES INTRAMUSCULARLY INTO THE PATIENT.

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

BayRho-D Full 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.
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 number of factors beyond our control 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

BayRho-D Full Dose is available in individual and multiple-pack single dose syringes with attached needles and vials.

<u>NDC Number</u>	<u>Size</u>
0026-0631-02	Syringe

STORAGE

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

CAUTION

R_x only

U.S. federal law prohibits dispensing without prescription.

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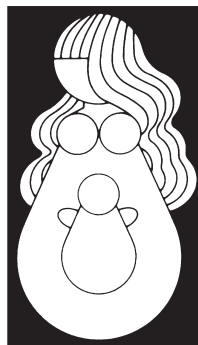
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The Rh Factor and Your Pregnancy

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

BayRho-D®, Rh₀(D) Immune Globulin (Human) can prevent hemolytic disease of the newborn, provided Rh positive antibodies do not already reside in your bloodstream.

BayRho-D is a specially prepared gamma globulin with a high level of preformed antibodies against Rh positive blood cells. The injection of BayRho-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.

BayRho-D Full Dose — When Prescribed**Pregnancy and Other Obstetric Conditions Pertaining to Rh Negative Women**

BayRho-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 BayRho-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 BayRho-D is not required.

Another injection of BayRho-D Full Dose is administered within 72 hours of delivery of an Rh positive baby.

Blood Transfusion

BayRho-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.

BayRho-D Mini-Dose — When Prescribed

A single dose of BayRho-D Mini-Dose may be prescribed for an Rh negative woman instead of BayRho-D Full Dose in the event of miscarriage or other termination of pregnancy occurring **prior** to 13 weeks' gestation. BayRho-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 BayRho-D Again?

BayRho-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 BayRho-D. This is why with each pregnancy it is important to have BayRho-D injections within the prescribed time period.

Reactions to BayRho-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 BayRho-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 BayRho-D, hemolytic disease of the newborn can be reduced to its lowest possible rate of incidence.

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**Bayer Corporation**

Pharmaceutical Division

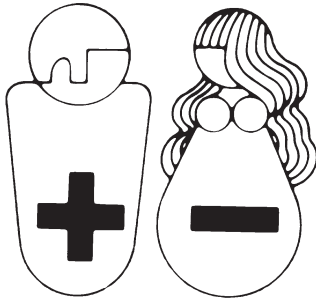
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Development of Hemolytic Disease

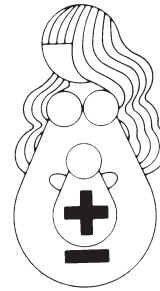
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Rh positive (+) father.
Rh negative (-) mother.



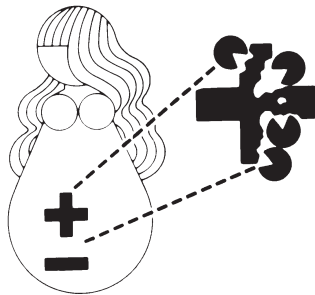
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Pregnancy: Rh- mother is carrying Rh+ baby.



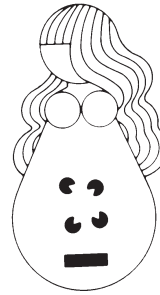
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The passage of Rh + blood from the baby to the mother's bloodstream happens most often at delivery, but can also occur during miscarriage, other termination of pregnancy, amniocentesis, or due to injury or trauma.



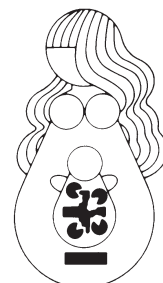
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Rh+ antibodies stay in your bloodstream, ready to attack invading Rh+ blood cells, for many years to come.



5

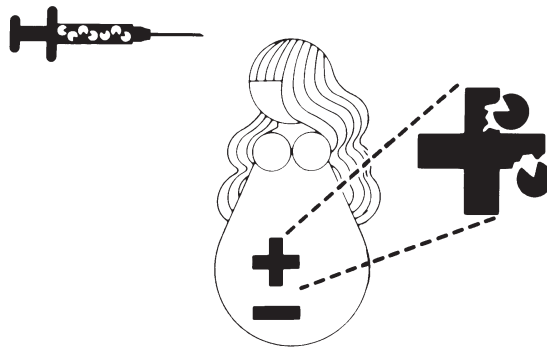
Next pregnancy, mother's Rh+ antibodies enter baby's Rh+ bloodstream, attacking baby's blood cells and causing hemolytic disease of the newborn.



How BayRho-D Immune Globulin Can Prevent Hemolytic Disease

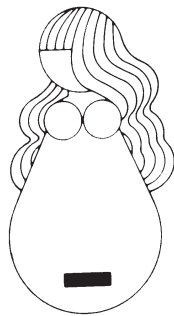
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You will probably be given two injections of BayRho-D Full Dose, one at the 28th week of your pregnancy and another within 72 hours of delivery, miscarriage or other termination of pregnancy. A single injection of BayRho-D Mini-Dose may be prescribed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



2

BayRho-D immunization prevents formation of mother's own Rh+ antibodies. Mother's bloodstream remains free of Rh+ antibodies.



3

Next pregnancy, baby develops normally. BayRho-D should be administered following delivery, miscarriage, or other termination of pregnancy to continue protection if baby is Rh+.

