Tear along perforation

3070334

3070334

Hyper**RHO**® S/D Full Dose

Rh_o(D) Immune Globulin (Human)

1500 IU
Solvent/Detergent Treated

DESCRIPTION

Rh_o(D) Immune Globulin (Human) — Hyper**RHO**® S/D Full 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 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. Hyper**RHO** 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 glycine. Hyper**RHO** S/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 1500 IU. Each single dose syringe contains sufficient anti-Rh_o(D) to effectively suppress the immunizing potential of 15 mL of Rh_o(D) positive red blood cells.(2-4)

The removal and inactivation of spiked model enveloped and non-enveloped viruses during the manufacturing process for Hyper**RHO** S/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 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.(18-21)

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

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

Rh hemolytic disease of the newborn is the result of the active immunization of an Rh_o(D) negative mother by Rh_o(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) Hyper**RHO** S/D Full Dose acts by suppressing the immune response of Rh_o(D) negative individuals to Rh_o(D) positive red blood cells. The mechanism of action of Hyper**RHO** S/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 Pollock(11) 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), 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

Pregnancy and Other Obstetric Conditions

Hyper**RHO** S/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 Hyper**RHO** S/D Full Dose is administered antepartum, it is essential that the mother receive another dose of Hyper**RHO** S/D Full Dose after delivery of an Rh_o(D) positive infant.

If the father can be determined to be Rh_o(D) negative, Hyper**RHO** S/D Full Dose need not be given.

Hyper**RHO** S/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 Hyper**RHO** S/D Full Dose should be administered to the mother.

Transfusion

Hyper**RHO** S/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

HyperRHO** S/D Full 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 LLC.**

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 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 Hyper**RHO** S/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.

Leaflet Informasi Pasien

Hyper**RHO**® S/D Full Dose

Rho(D) Immune Globulin (Human)
1500 IU
cairan injeksi intramuskular

Mohon membaca leaflet ini secara seksama sebelum menggunakannya

- Simpan leaflet ini. Anda mungkin membutuhkannya untuk dibaca kembali.
- Jika terdapat pertanyaan, tanyakan kepada dokter atau apoteker Anda.
- Obat ini diberikan untuk Anda. Jangan berikan kepada orang lain. Hal ini dapat membahayakan mereka, meskipun memiliki gejala yang sama dengan Anda.
- Jika anda mengalami efek samping serius, atau jika Anda mengalami efek samping yang tidak disebutkan dalam leaflet ini, beritahukan kepada dokter atau apoteker Anda.

Informasi yang tercantum dalam leaflet ini:

KANDUNGAN DAN KEGUNAAN HYPERRHO S/D FULL DOSE

Hyper**RHO** S/D Full Dose dapat mencegah penyakit hemolitik pada bayi baru lahir yang disebabkan oleh perbedaan factor Rhesus (Rh). Jika Anda seorang ibu dengan Rho (D) negatif yang mengandung bayi Rho (D) positif, Anda dapat menerima suntikan Hyper**RHO** S/D Full Dose jika:

- Anda belum tersensitisasi terhadap faktor Rho (D)
- anak Anda Rho (D) positif

Dokter Anda akan memutuskan untuk memberikan Anda Hyper**RHO** S/D Full Dose pada sekitar 28 minggu kehamilan dan pemberian dosis kedua dalam waktu 72 jam setelah melahirkan.

Jika Ayah dari bayi memiliki Rho(D) negatif, Hyper**RHO** S/D Full Dose tidak perlu diberikan.

Anda mungkin akan diberikan Hyper**RHO** S/D Full Dose jika Anda telah mengalami aborsi spontan atau diinduksi, kehamilan ektopik terganggu, amniosentesis atau trauma abdomen.

Bayi Anda tidak akan pernah menerima Hyper**RHO** S/D Full Dose.

Anda mungkin diberikan Hyper**RHO** S/D Full Dose jika Anda memiliki Rho(D) negatif tetapi telah menerima transfusi darah dari Rho(D) positif.

Jika Anda memiliki pertanyaan mengenai penggunaan Hyper**RHO** S/D Full Dose, mohon tanyakan kepada dokter Anda.

HAL YANG HARUS DIKETAHUI SEBELUM MENGGUNAKAN HYPERRHO S/D FULL DOSE

Hyper**RHO** S/D Full Dose tidak boleh diberikan kepada bayi yang baru lahir.

Jangan gunakan HyperRHO S/D Full Dose

- jika Anda Rh positif,
- jika Anda memiliki reaksi alergi terhadap anti-D immunoglobulin manusia atau produk darah lainnya,
- jika Anda alergi terhadap salah satu bahan pada Hyper**RHO** S/D Full Dose,
- jika Anda memiliki defisiensi IgA dengan antibodi anti-IgA.

Jika ini terjadi pada Anda, walaupun sudah berlalu, segera hubungi dokter Anda.

Gunakan HyperRHO dengan hati-hati

- jika Anda memiliki trombositopenia (defisiensi trombosit yang merupakan fragmen sel yang membantu dalam koagulasi) atau gangguan pendarahan lainnya karena obat yang diberikan melalui intramuskular (ke dalam vena) menyebabkan komplikasi perdarahan.
- jika Anda memiliki riwayat reaksi alergi terhadap obat yang terbuat dari immunoglobulin manusia.

Gunakan jarum suntik imunoglobulin sekali. Jangan gunakan atau biarkan orang lain menggunakan jarum suntik yang sama untuk kedua kalinya.

Ketika obat-obatan terbuat dari darah manusia atau plasma, langkah-langkah tertentu dilakukan untuk mencegah infeksi ditularkan kepada pasien. Hal ini termasuk:

- pemilihan darah dan donor plasma dengan hati-hati untuk memastikan mereka yang berisiko membawa infeksi dikecualikan,
- pengujian setiap donasi dan kumpulan plasma untuk tanda-tanda infeksi/virus
- melakukan langkah-langkah dalam pemrosesan darah atau plasma yang dapat menginaktivasi atau menghi-langkan virus.

Terlepas dari langkah-langkah ini, ketika obat-obatan yang terbuat dari darah atau plasma manusia diberikan, kemungkinan penularan infeksi tidak dapat sepenuhnya dihindari. Ini juga berlaku untuk virus yang tidak dikenal atau sedang muncul atau jenis infeksi lainnya.

Sangat disarankan agar setiap kali Anda menerima dosis Hyper**RHO** S/D Full Dose, nama dan nomor bets produk dicatat untuk menjaga catatan bets yang telah digunakan.

Penggunaan obat-obatan lain

Beri tahu dokter Anda jika Anda sedang mengonsumsi atau baru saja mengonsumsi obat lain termasuk obat-obatan yang didapat tanpa resep.

Antibodi lain dalam Hyper**RHO** S/D Full Dose dapat mengganggu respon terhadap vaksin aktif seperti campak, gondong, polio atau rubella. Karena itu, jika Anda sudah diberikan vaksin ini, Anda harus menunggu selama tiga bulan untuk menerima vaksin aktif lainnya. Anda harus memberi tahu dokter Anda tentang masalah ini.

colors: **Black**

K/P Corporation Job No. 155033
Client: Grifols Therapeutics LLC Cat. No. 3070334
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ID: 1,13,20 Size: 9" x 21" (Spec 9028495 / 08620647 / 06-1422) Proof **1**

Kehamilan dan menyusui

Mintalah nasihat dokter atau apoteker Anda sebelum mengonsumsi obat apa pun.

Jika Anda hamil atau sedang menyusui, Anda hanya dapat diberikan Hyper**RHO** S/D Full Dose jika dokter Anda memutuskan bahwa ini sangat dibutuhkan.

CARA MENGGUNAKAN HYPERRHO S/D FULL DOSE

Hyper**RHO** S/D Full Dose hanya untuk injeksi intramuskular. Pemberian Hyper**RHO** S/D Full Dose dilakukan oleh staf kesehatan dan tidak boleh dilakukan sendiri. Dosis yang akan diberikan kepada Anda disesuaikan dengan kondisi medis Anda.

Hyper**RHO** S/D Full Dose tidak boleh diberikan kepada bayi yang baru lahir.

Jika Anda lupa menggunakan HyperRHO S/D Full Dose

Beritahukan kepada dokter Anda dan ikuti petunjuknya.

EFEK SAMPING

Seperti halnya obat-obatan lain, Hyper**RHO** S/D Full Dose dapat menyebabkan efek samping, walaupun tidak semua orang mengalaminya.

Efek samping Hyper**RHO** S/D Full Dose jarang terjadi pada individu yang memiliki Rho(D) negatif dan terutama terdiri dari:

- Sedikit rasa sakit di area injeksi dan sedikit peningkatan suhu
- Dalam kasus yang sangat jarang, reaksi alergi dapat terjadi, dokter Anda akan melakukan tindakan yang tepat

Pelaporan efek samping

Jika terjadi efek samping yang serius, atau Anda merasa mengalami efek samping yang tidak terdapat di dalam leaflet ini, segera beritahukan dokter Anda.

CARA PENYIMPANAN HYPERRHO S/D FULL DOSE

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Simpan pada suhu 2 - 8 ºC. Jangan dibekukan. Simpan vial dalam kemasan karton asli.

Jangan gunakan Hyper**RHO** S/D Full Dose setelah tanggal kedaluwarsa yang tercantum pada label *syringe* dan karton.

Jangan gunakan Hyper**RHO** S/D Full Dose jika Anda melihat larutan keruh atau memiliki deposit.

Setiap produk yang tidak digunakan atau bahan limbah harus dibuang sesuai dengan ketentuan.

INFORMASI LAINNYA

Kandungan dalam HyperRHO S/D Full Dose

Zat aktif dari Hyper**RHO** S/D Full Dose adalah Rho(D) Immune Globulin (Human).

Komposisi lainnya adalah glisin dan air untuk injeksi.

Bentuk dan isi kemasan HyperRHO S/D Full Dose

Hyper**RHO** S/D Full Dose merupakan larutan steril tak berwarna hingga kuning pucat atau pink.

Hyper**RHO** S/D Full Dose merupakan larutan 1 mL dalam *pre-filled syringe* dengan jarum dan dikemas dengan 1 *syringe* per karton.

Hyper**RHO** S/D Full Dose tidak mengandung pengawet, dengan *latex-free delivery system.*

HARUS DENGAN RESEP DOKTER

KEMASAN DAN NOMOR REGISTRASI

Hyper**RHO** S/D, Dus, 1 syringe @ 1 mL.
Reg. No:

Diimpor oleh:
PT Combiphar
Bandung Barat, Indonesia

Diproduksi oleh:
Grifols Therapeutics LLC
Research Triangle Park, NC 27709 USA

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 Rh_O(D) Immune Globulin (Human) — Hyper**RHO**® S/D Full Dose. It is also not known whether Hyper**RHO** S/D Full Dose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hyper**RHO** S/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 HYPER**RHO** S/D FULL DOSE INTRAVENOUSLY. INJECT ONLY INTRAMUSCULARLY. NEVER ADMINISTER TO THE NEONATE.

Pregnancy and Other Obstetric Conditions

1. For postpartum prophylaxis, administer one syringe of Hyper**RHO** S/D Full Dose, preferably within 72 hours of delivery. Although a lesser degree of protection is afforded if Rh antibody is administered beyond the 72-hour period, Hyper**RHO** S/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 full dose syringe of Hyper**RHO** S/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 syringes of Hyper**RHO** S/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 syringes (e.g., if 1.4, give 2 syringes).
2. For antenatal prophylaxis, one full dose syringe of Hyper**RHO** S/D Full Dose is administered at approximately 28 weeks' gestation. This **must** be followed by another full 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 a full dose of Hyper**RHO** S/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 a Hyper**RHO** S/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 Hyper**RHO**® S/D Mini-Dose may be used instead of Hyper**RHO** S/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 a Hyper**RHO** S/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 Hyper**RHO** S/D Full Dose at 13 to 18 weeks' gestation, another full dose should be given at 26 to 28 weeks. To maintain protection throughout pregnancy, the level of passively acquired anti-Rh_O(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 Hyper**RHO** S/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)

Transfusion

In the case of a transfusion of Rh_O(D) positive red cells to an Rh_O(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 syringes of Hyper**RHO** S/D Full Dose to be administered.

If the dose calculated results in a fraction, the next higher whole number of syringes should be administered (e.g., if 1.4, give 2 syringes). Hyper**RHO** S/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. Hyper**RHO** S/D Full 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.(17)

A. Single Syringe Dose

INJECT ENTIRE CONTENTS OF THE SYRINGE INTO THE INDIVIDUAL INTRAMUSCULARLY.

B. Multiple Syringe Dose

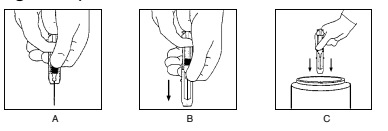
1. Calculate the number of syringes of Hyper**RHO** S/D Full Dose to be given (see Dosage section).
2. The total volume of Hyper**RHO** S/D Full Dose can be given in divided doses at different sites at one time or the total dose may be divided and injected at intervals, provided the total dosage is given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

Hyper**RHO** S/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. [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 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 Full Dose available in a single dose syringe with attached needle.

STORAGE

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

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