

# HyperRAB, 300 IU/mL Rabies Immune Globulin (Human)

## QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance: rabies immune globulin (human)

Each 1 mL contains 300 IU rabies immune globulin (human).

1 mL vial 300 IU  
5 mL vial 1500 IU

Total protein: 15 to 18%, pH 4.1 to 4.8

Potency: standardized against the U.S. Standard rabies immune globulin to contain a potency of  $\geq$  300 IU/mL. The U.S. unit of potency is equivalent to the international unit (IU) for rabies antibody.

HyperRAB contains no preservative.

Produced from plasma of human donors.

For a full list of excipients, see section 6.1.

## PHARMACEUTICAL FORM

Solution for infiltration and intramuscular injection

The solution is clear or slightly opalescent, and colorless or pale yellow or light brown.

## CLINICAL PARTICULARS

### Therapeutic indications

HyperRAB is a human rabies immune globulin indicated for postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies.

### Limitations of Use

Persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer should receive only vaccine.

For unvaccinated persons, the combination of HyperRAB and vaccine is recommended for both bite and nonbite exposures regardless of the time interval between exposure and initiation of postexposure prophylaxis.

Beyond 7 days (after the first vaccine dose), HyperRAB is not indicated since an antibody response to vaccine is presumed to have occurred.

### Posology and method of administration

For infiltration and intramuscular use only.

The strength of HyperRAB is 300 IU/mL.

### Posology

Use HyperRAB in combination with rabies vaccine series to be effective. Do not use HyperRAB alone for prevention.

Administer HyperRAB within 7 days after the first dose of rabies vaccine.

### Rabies Postexposure Prophylaxis Schedule\*

Vaccination Status	Treatment	Regimen†
Not previously vaccinated	Wound cleansing	<ul style="list-style-type: none"> <li>Cleanse all wounds immediately and thoroughly with soap and water.</li> <li>Irrigate the wounds with a virucidal agent such as a povidone-iodine solution, if available.</li> </ul>
	HyperRAB 20 IU/kg body weight OR 0.0665 mL/kg body weight Single-dose	<ul style="list-style-type: none"> <li>Administer HyperRAB as soon as possible after exposure, preferably at the time of the first vaccine dose.</li> <li>Infiltrate the full dose of HyperRAB thoroughly in the area around and into the wound(s), if anatomically feasible. Inject the remainder, if any, intramuscularly at an anatomical site distant from the site of vaccine administration.</li> <li>Do not exceed the recommended dose of HyperRAB, otherwise the active production of rabies antibody may be partially suppressed.</li> <li>Use separate syringes, needles, and anatomical injection sites for HyperRAB and for rabies vaccine.</li> </ul>
	Rabies Vaccine	<ul style="list-style-type: none"> <li>Administer rabies vaccine on day 0†.</li> <li>Complete a rabies vaccination series for previously unvaccinated persons.</li> </ul>
Previously vaccinated§	Wound cleansing	<ul style="list-style-type: none"> <li>Cleanse all wounds immediately and thoroughly with soap and water.</li> <li>Irrigate the wounds with a virucidal agent such as a povidone-iodine solution, if available.</li> </ul>
	HyperRAB	<ul style="list-style-type: none"> <li>Do not administer HyperRAB.</li> </ul>
	Rabies Vaccine	<ul style="list-style-type: none"> <li>Administer rabies vaccine on day 0†.</li> <li>Complete a rabies vaccination series for previously vaccinated persons.†</li> </ul>

\* Adapted from reference 1.

† These regimens are applicable for all age groups, including children.

‡ Day 0 is the day the first dose of vaccine is administered. Refer to vaccine manufacturer's instructions or to the recommendations of the United States Advisory Committee on Immunization Practices (ACIP) for appropriate rabies vaccine formulations, schedules and dosages.

§ Any person with a history of rabies vaccination and a documented history of antibody response to the prior vaccination.

### Preparation

- Calculate the volume of HyperRAB for the recommended dose of 20 IU/kg.
- Ensure the correct strength is used for the calculation. HyperRAB is formulated with a

## HyperRAB, 300 IU/mL

Rabies Immune Globulin (Human)

Larutan untuk injeksi intramuskular dan infiltrasi

### Mohon membaca leaflet ini secara seksama sebelum menggunakannya.

Leaflet ini memuat informasi penting mengenai obat ini. Jika Anda memiliki pertanyaan, hubungi dokter atau apoteker Anda.

Obat ini diberikan untuk Anda/pengobatan Anda.

### APA KEGUNAAN OBAT INI?

HyperRAB adalah larutan imunoglobulin anti-rabies yang digunakan untuk pencegahan terhadap rabies.

Obat ini termasuk ke dalam kelompok farmakoterapi yang disebut imunosera dan imunoglobulin.

HyperRAB diindikasikan untuk pencegahan rabies postexposure, diberikan bersamaan dengan vaksin rabies, untuk semua pasien yang dicurigai terkena rabies.

### Batasan penggunaan

- Pasien yang sebelumnya telah diberikan vaksin rabies dan sudah dipastikan memiliki titer antibodi rabies yang adekuat hanya perlu menerima vaksin.

- Bagi pasien yang belum divaksinasi, kombinasi HyperRAB dan vaksin direkomendasikan baik untuk yang terpajan melalui gigitan maupun bukan gigitan tanpa memperhatikan interval waktu antara saat terpajan dan saat pemberian profilaksis postexposure.

- Setelah 7 hari (setelah pemberian dosis vaksin pertama), HyperRAB tidak diberikan karena respon antibodi terhadap vaksin kemungkinan telah terjadi.

Vaksin rabies harus selalu diberikan bersamaan dengan HyperRAB selama tidak ada kontraindikasi terhadap penggunaan vaksin. Jangan pernah gunakan HyperRAB jika terbukti sudah memiliki titer vaksin yang adekuat.

### SEBELUM MENGGUNAKAN HYPERRAB

#### Jangan gunakan HyperRAB jika:

- Jika Anda telah menerima vaksin rabies lengkap. Mohon beritahu dokter Anda jika Anda telah menerima vaksin rabies.

#### Peringatan khusus terhadap penggunaan HyperRAB

- Anda mungkin akan mengalami reaksi alergi parah, termasuk anafilaksis, terutama dalam penggunaan HyperRAB jika Anda memiliki riwayat medis berupa reaksi alergi terhadap pemberian imunoglobulin manusia. Jika Anda sedang menggunakan epinefrin, reaksi alergi dapat terjadi.
- Anda mungkin akan mengalami reaksi alergi parah, termasuk anafilaksis, dalam penggunaan HyperRAB jika Anda memiliki defisiensi imunoglobulin A (IgA).

strength of 300 IU/mL. The predecessor product, HyperRAB S/D was formulated at 150 IU/mL. The volume required of HyperRAB (300 IU/mL) to achieve the recommended dose of 20 IU/kg is approximately one half of that required for the previous HyperRAB S/D (150 IU/mL).

- Visually inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever solution and container permit. HyperRAB is a clear or slightly opalescent, and colorless or pale yellow or light brown sterile solution.

- Do not use HyperRAB if the product shows any sign of tampering. Notify Grifols Therapeutics LLC immediately.

- Do not freeze. Do not use any solution that has been frozen.

### Method of administration

- Administer HyperRAB at the time of the first vaccine dose (day 0), but no later than day 7.
- Infiltrate the full dose of HyperRAB in the area around the wound, if anatomically feasible. Dilute HyperRAB with an equal volume of dextrose, 5% (D5W), if additional volume is needed to infiltrate the entire wound. Do not dilute with normal saline.

- Inject the remainder, if any, of the HyperRAB dose intramuscularly into the deltoid muscle of the upper arm or into the lateral thigh muscle, and distant from the site of vaccine administration.

- Do not administer HyperRAB in the same syringe or needle or in the same anatomic site as vaccine.

### Contraindications

None.

### Special warnings and precautions for use

#### Hypersensitivity reactions

Severe hypersensitivity reactions may occur with HyperRAB. Patients with a history of prior systemic allergic reactions to human immunoglobulin preparations are at a greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available for treatment of acute allergic symptoms, should they occur.

Patients with isolated immunoglobulin A (IgA) deficiency may develop severe hypersensitivity reactions to HyperRAB, or subsequently, to the administration of blood products that contain IgA.

#### Transmissible infectious agents

HyperRAB is purified from human plasma obtained from healthy donors. When medicinal biological products are administered, infectious diseases due to transmission of pathogens cannot be totally excluded. However, in the case of products prepared from human plasma, the risk of transmission of pathogens is reduced by: (1) epidemiological controls on the donor population and selection of individual donors by a medical interview and screening of individual donations and plasma pools for viral infection markers; (2) testing of plasma for hepatitis C virus (HCV), human immunodeficiency virus (HIV), hepatitis B virus (HBV), HAV and human parvovirus (B19V) genomic material; and (3) manufacturing procedures with demonstrated capacity to inactivate/remove pathogens.

There is reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to viral safety.

#### Elderly population

Safety and effectiveness in geriatric population have not been established.

#### Pediatric population

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

#### Information for patients

Discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient.

Inform the patient who is allergic to human immune globulin products that severe, potentially life-threatening allergic reactions could occur.

Inform the patient who is deficient in IgA the potential for developing anti-IgA antibodies and severe potentially life threatening allergic reactions.

Inform the patient that HyperRAB is made from human plasma and may carry a risk of transmitting infectious agents that can cause disease. While the risk that HyperRAB can transmit an infectious agent has been reduced by screening plasma donors for prior exposure,

HyperRAB dimurnikan dari plasma manusia yang didapat dari donor sehat. Ketika obat dari produk biologi diberikan, terjadinya infeksi yang disebabkan oleh penularan patogen tidak dapat dihindarkan sepenuhnya. Namun, dalam kasus produk dengan sediaan dari plasma manusia, risiko penularan patogen dapat diminimalisir dengan cara: (1) kontrol epidemiologis pada populasi donor dan pemilihan donor individu melalui wawancara medis dan skrining terhadap plasma donor dan adanya penanda (marker) infeksi virus saat pengumpulan plasma (2) pengujian plasma untuk virus hepatitis C (HCV), human immunodeficiency virus (HIV), virus hepatitis B (HBV), virus hepatitis A (HAV), dan materi genetik human parvovirus (B19V); dan (3) menginaktivasi serta menghilangkan patogen selama proses produksi.

Imunoglobulin tidak berkaitan dengan infeksi hepatitis A atau kemungkinan terinfeksi parvovirus B19 karena antibodi terhadap infeksi ini, yang terdapat dalam produk, bersifat melindungi.

Sangat direkomendasikan bagi petugas kesehatan saat memberikan HyperRAB untuk mencatat nama obat dan nomor batch sebagai simpanan data batch yang digunakan.

Informasikan kepada dokter Anda jika satu atau lebih faktor risiko yang disebutkan di atas terjadi kepada Anda.

Sebelum melakukan pengobatan dengan HyperRAB, beritahu dokter Anda jika:

- Anda hamil, berencana untuk hamil, atau sedang menyusui.
- Anda sensitif terhadap makanan atau obat tertentu.
- Anda sedang dalam pengobatan menggunakan produk imunoglobulin, seperti HyperRAB, karena komponen vaksin tertentu (yang mengandung komponen virus hidup) dapat menjadi kurang efektif untuk Anda.
- Jika Anda berencana untuk divaksinasi, beritahu dokter atau perawat bahwa Anda sedang menggunakan HyperRAB. Antibodi pada HyperRAB dapat mencegah aktivitas vaksin.

### Anak-anak dan remaja

Keamanan dan efektifitas HyperRAB belum diketahui pada subjek pediatrik.

Informasikan kepada dokter atau apoteker Anda, jika Anda mengonsumsi obat lain termasuk obat tanpa resep dan suplemen makanan.

### BAGAIMANA CARA PENGGUNAANNYA?

Dosis dan regimen pengobatan hanya dapat ditentukan oleh dokter.

#### Jangan melebihi dosis yang direkomendasikan.

Anda akan menerima HyperRAB bersamaan dengan vaksin rabies. Namun, jika Anda sudah mendapatkan vaksin, Anda akan menerima HyperRAB hanya pada minggu pertama. Dokter Anda akan menentukan dosis HyperRAB.

Pertama, luka Anda akan dibersihkan menggunakan sabun dan air.

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