GRIFOLS

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 ≥ 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	• Cleanse all wounds immediately and thoroughly with soap and water. • Irrigate the wounds with a virucidal agent such as a povidone-iodine solution, if available.
	HyperRAB 20 IU/kg body weight OR 0.0665 mL/kg body weight Single-dose	• Administer HyperRAB as soon as possible after exposure, preferably at the time of the first vaccine dose. • 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. • Do not exceed the recommended dose of HyperRAB, otherwise the active production of rabies antibody may be partially suppressed. • Use separate syringes, needles, and anatomical injection sites for HyperRAB and for rabies vaccine.
	Rabies Vaccine	• Administer rabies vaccine on day 0‡. • Complete a rabies vaccination series for previously unvaccinated persons.
Previously vaccinated§	Wound cleansing	• Cleanse all wounds immediately and thoroughly with soap and water. • Irrigate the wounds with a virucidal agent such as a povidone-iodine solution, if available.
	HyperRAB	• Do not administer HyperRAB.
	Rabies Vaccine	• Administer rabies vaccine on day 0‡. • Complete a rabies vaccination series for previously vaccinated persons.†

* 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 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,

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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 beritahukan 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).

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, beritahukan 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, beritahukan 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.

DISETUJUI OLEH BPOM: 17 JULI 2024

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testing donated plasma, and including manufacturing steps with the capacity to inactivate and/or remove pathogens, the patient should report any symptoms that concern them.

Interactions with other medicaments and other forms of interactions

- Do not administer repeated doses of HyperRAB once vaccine treatment has been initiated as this could prevent the full expression of active immunity expected from the rabies vaccine.
- Other antibodies in the HyperRAB preparation may interfere with the response to live vaccines such as measles, mumps, polio or rubella. Defer immunization with live vaccines for 4 months after HyperRAB administration.

Pregnancy and lactation

Pregnancy

There are no data with HyperRAB use in pregnant women to inform a drug-associated risk. Animal reproduction studies have not been conducted with HyperRAB. It is not known whether HyperRAB can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. HyperRAB should be given to a pregnant woman only if clearly needed.

Lactation

There is no information regarding the presence of HyperRAB in human milk, the effect on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for HyperRAB and any potential adverse effects on the breastfed infant from HyperRAB.

Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

Undesirable effects

Summary safety profile

The most common adverse reactions in >5% of subjects during clinical trials were injection site pain, headache, injection site nodule, abdominal pain, diarrhea, flatulence, nasal congestion, and oropharyngeal pain.

Postmarketing experience

There are no data on the postmarketing use of HyperRAB (300 IU/mL). The following adverse reactions have been identified during post approval use of the predecessor formulation, HyperRAB S/D. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Among patients treated with HyperRAB S/D, cases of allergic/hypersensitivity reactions including anaphylaxis have been reported. Soreness at the site of injection (injection site pain) may be observed following intramuscular injection of immune globulins. Sensitization to repeated injections has occurred occasionally in immunoglobulin-deficient patients.

The following have been identified as the most frequently reported post-marketing adverse reactions:

Immune system disorder	Anaphylactic reaction*, hypersensitivity*
Nervous system disorders	Hypoesthesia
Gastrointestinal disorders	Nausea
Musculoskeletal and connective tissue disorders	Arthralgia, myalgia, pain in extremity

* These reactions have been manifested by dizziness, paresthesia, rash, flushing, dyspnea, tachypnea, oropharyngeal pain, hyperhidrosis, and erythema

Clinical trials experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The new formulation for HyperRAB is manufactured using caprylate/chromatography purification and has a rabies antibody concentration of 300 IU/mL. The previous formulation, HyperRAB S/D, was manufactured using a solvent detergent process and had a rabies antibody concentration of 150 IU/mL. These products were evaluated in 2 clinical trials in a total of 20 healthy subjects using a 20 IU/kg single-dose. The initial study evaluated the original 150 IU/mL HyperRAB S/D in 8 subjects and the second study evaluated HyperRAB in 12 subjects. The original study of HyperRAB S/D reported headache (1/8; 13%).

In the study with HyperRAB at 300 IU/mL, 5 subjects (5/12; 42%) experienced at least 1 adverse reaction. These were: injection site pain (4/12; 33%), injection site nodule (1/12; 8%), abdominal pain (1/12; 8%), diarrhea (1/12; 8%), flatulence (1/12; 8%), headache (1/12; 8%), nasal congestion (1/12; 8%), and oropharyngeal pain (1/12; 8%).

Overdose

Because rabies immune globulin (human) may partially suppress active production of antibody in response to the rabies vaccine, do not give more than the recommended dose of rabies immune globulin (human).

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: immune sera and immunoglobulins, human rabies immunoglobulin, ATC code: J06BB05

Mechanism of action

HyperRAB provides immediate, passive, rabies virus neutralizing antibody coverage until the previously unvaccinated patient responds to rabies vaccine by actively producing antibodies.

Pharmacodynamic effects

Human rabies immunoglobulin contains mainly immunoglobulin G (IgG) with a specifically high content of antibodies against rabies virus.

Clinical efficacy and safety

HyperRAB was administered to a total of 20 healthy adult subjects in two clinical trials. A single intramuscular dose of 20 IU/kg HyperRAB (12 subjects) or HyperRAB S/D (8 subjects) was administered and rabies neutralizing antibody titers were monitored in serum for 21 days. Administration of both HyperRAB formulations resulted in detectable titers of neutralizing antibodies to the rabies virus that persisted throughout the 21 day study period (Figure 2).

Pharmacokinetic properties

In a clinical study of 12 healthy human subjects receiving a 20 IU/kg intramuscular dose of HyperRAB detectable passive rabies neutralizing antibody was present by 24 hours and persisted through the 21 day follow-up evaluation period. Figure 1 shows the mean levels of rabies virus antibodies in IU/mL across the 21 day evaluation period and indicates that the titer remains stable during this period. This level of passive rabies neutralizing antibody is similar to that reported in the literature for administration of human rabies immune globulin, and is clinically important because it provides interim protection until the host immune response to rabies vaccine produces definitive protective titers of neutralizing rabies antibody (therefore the rabies vaccine series is also essential).

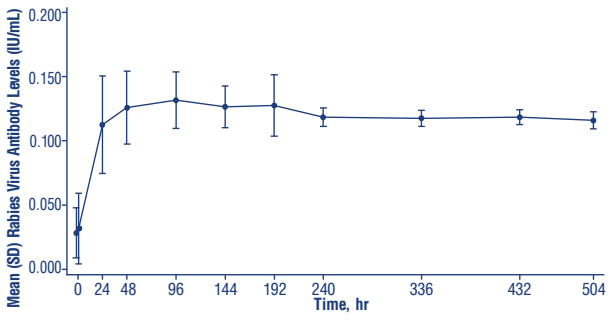

Figure 1: Mean (Standard Deviation) Rabies Virus Neutralizing Antibody Levels (IU/mL) versus Time following a Single 20 IU/kg Dose of HyperRAB (300 IU/mL) by Intramuscular Injection

The previous formulation, HyperRAB S/D, was studied in 8 healthy subjects over 21 days. As with the new formulation, rabies neutralizing antibody was present by 24 hours and persisted through the 21 day follow up period (Figure 2).

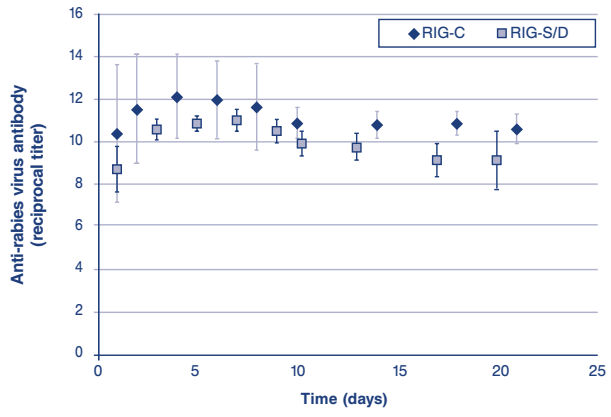

Figure 2: Reciprocal of Anti-Rabies Virus Neutralizing Antibody Titer Following a Single 20 IU/kg Dose of HyperRAB (300 IU/mL; RIG-C) or HyperRAB S/D (150 IU/mL; RIG-S/D) Product (mean [standard deviation])

Preclinical safety data

There is no preclinical safety statement available.

PHARMACEUTICAL PARTICULARS

List of excipients

Water for Injection, USP, EP
Glycine, USP, EP

Incompatibilities

This medicinal product must not be mixed with other medicinal products.

Shelf life

36 months

Special precautions for storage

- Store HyperRAB at 2 to 8°C. Do not freeze.
  - HyperRAB may be stored at room temperatures not to exceed 25°C for up to 6 months.
  - Use within 6 months after removal from refrigeration at any time prior to the expiration date, after which the product must be used or discarded. Do not return to refrigeration.
- Do not use after expiration date printed on the label.
- Discard unused portion.
- Do not use the medicine if particulate matter and/or discoloration are present.

Nature and contents of container

HyperRAB is supplied in 1 mL and 5 mL glass single-dose vials of ready-to-use solution with a chlorobutyl stopper, aluminum overseal, plastic flip top and shrink band.

HyperRAB contains no preservative and is not made with natural rubber latex.

Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

MARKETING AUTHORIZATION HOLDER

Grifols Therapeutics LLC, Research Triangle Park, NC 27709, USA

MARKETING AUTHORIZATION NUMBER(S)

1 mL - DKI9590500743A1
5 mL - DKI9590500743A1

DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization: 27 Nov 1995

DATE OF REVISION OF TEXT

06/2022

HARUS DENGAN RESEP DOKTER

PACKAGING AND REGISTRATION NUMBER

HyperRAB Dus, 1 vial @1 mL. Reg. No: DKI9590500743A1
HyperRAB Dus, 1 vial @5 mL. Reg. No: DKI9590500743A1

Imported by:
PT. Dipa Pharmalab Intersains
Majalengka - Indonesia

Manufactured by:

GRIFOLS

Grifols Therapeutics LLC
Research Triangle Park, NC 27709 USA

3063316

Kedua, dokter akan menyuntikkan HyperRAB ke dalam dan sekitar luka Anda. Anda harus menerima dosis lengkap di sekitar luka walaupun dokter Anda mungkin akan menyuntikkan sisanya ke bagian paha atau otot lengan atas.

Ketiga, dokter Anda akan menyuntikkan vaksin rabies ke bagian paha atau otot lengan atas lainnya.

Cara pemberian

Penyuntikan hanya diberikan melalui infiltrasi jaringan atau intramuskular.

HyperRAB tidak boleh diberikan melalui intravena.

Jika Anda secara tidak sengaja melebihi dosis yang dianjurkan

Jangan menggunakan melebihi dosis yang dianjurkan karena HyperRAB dapat menurunkan sebagian kemampuan Anda untuk membentuk antibodi terhadap virus rabies.

Jika Anda lupa menggunakan HyperRAB

Jika Anda lupa menggunakan pada waktu yang ditentukan, konsultasikan ke dokter Anda.

Jangan menggunakan dosis ganda.

Bagaimana Anda dapat berkontribusi terhadap keberhasilan penggunaan?

Patuhi regimen vaksinasi rabies yang direkomendasikan oleh dokter. Untuk mencegah rabies, Anda harus menerima semua booster vaksinasi sesuai yang dijadwalkan oleh dokter. Jika Anda memiliki pertanyaan lebih lanjut mengenai penggunaan obat ini, konsultasikan dengan dokter atau apoteker Anda.

EFEK SAMPING

Seperti umumnya obat, penggunaan HyperRAB dapat menyebabkan efek samping pada beberapa pengguna. Jangan khawatir dengan daftar efek samping ini. Anda mungkin tidak mengalami efek samping tersebut.

Efek samping yang paling umum terjadi dalam uji klinis adalah nyeri pada lokasi injeksi, sakit kepala, nodul pada lokasi injeksi, sakit perut, diare, buang angin (flatus), hidung tersumbat, dan sakit tenggorokan.

Diantara pasien yang diobati dengan HyperRAB, kasus reaksi alergi termasuk anafilaksis telah dilaporkan. Nyeri pada lokasi injeksi dapat diamati setelah penyuntikan imunoglobulin secara intramuskular.

Efek samping berikut telah teridentifikasi dan dilaporkan selama penggunaan pasca-pemasaran:

Gangguan sistem imun	Reaksi anafilaksis* Hipersensitivitas*
Gangguan sistem saraf	Baal (Hipoestesia)
Gangguan pencernaan	Mual
Gangguan jaringan sendi dan ikat	Nyeri sendi (Artralgia), nyeri otot (Myalgia), nyeri pada anggota gerak

* Reaksi di atas dimanifestasikan seperti pusing, paraestesia (kesemutan), ruam, flushing (sensasi hangat dan kemerahan), dispnea (sesak nafas), takipnea (nafas cepat), sakit tenggorokan, keringat berlebih, dan eritema (kemerahan).

Sangat penting untuk melaporkan kepada dokter Anda jika terjadi efek samping yang mengkhawatirkan. Anda dapat meminta informasi lengkap yang tersedia untuk ahli kesehatan dari dokter Anda.

Jika ada efek samping yang serius, atau jika Anda melihat terdapat efek samping yang tidak tercantum dalam leaflet ini, segera konsultasikan dengan dokter Anda.

BAGAIMANA OBAT INI HARUS DISIMPAN?

- Jangan gunakan obat ini setelah tanggal kedaluwarsa (exp. date) yang tercantum pada kemasan/label syringe. Tanggal kedaluwarsa adalah hari terakhir pada bulan tersebut.

Kondisi penyimpanan:

- Simpan HyperRAB pada suhu 2-8°C. Jangan dibekukan.
  - HyperRAB dapat disimpan pada suhu ruang, di bawah suhu 25°C selama 6 bulan.
  - Gunakan dalam waktu 6 bulan setelah dikeluarkan dari lemari pendingin sebelum tanggal kedaluwarsa, selanjutnya produk ini harus dibuang atau langsung digunakan. Jangan dikembalikan ke lemari pendingin.
- Jangan digunakan setelah tanggal kedaluwarsa yang tercantum pada kemasan.
- Buang sisa obat yang tidak digunakan.
- Jangan gunakan obat jika terdapat partikel dan/atau terjadi perubahan warna.

INFORMASI LAINNYA

- Selain zat aktif, obat ini juga mengandung:
  Glisin, Air untuk injeksi
- Bentuk HyperRAB dan isi kemasan:
  HyperRAB tersedia dalam kemasan vial larutan siap pakai dosis tunggal 1 mL dan 5 mL dengan potensi tidak kurang dari 300 IU/mL.
  Larutan bening atau opalescent, dan tidak berwarna atau kuning pucat atau cokelat terang.

HARUS DENGAN RESEP DOKTER

KEMASAN DAN NOMOR REGISTRASI

HyperRAB Dus, 1 vial @1 mL. Reg. No: DKI9590500743A1
HyperRAB Dus, 1 vial @5 mL. Reg. No: DKI9590500743A1

Diproduksi oleh:
Grifols Therapeutics LLC
North Carolina, USA

Diimpor oleh:
PT. Dipa Pharmalab Intersains
Majalengka - Indonesia