Rabies Immune Globulin
Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.310**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program, Standards and Quality		
Approval Date:	March 1, 2013	**Revised:**	May 15, 2020

	HyperRAB®	**KamRAB®**	**IMOGAM®**
Manufacturer	Grifols Therapeutics LLC. distributed by Grifols Canada Ltd.	Kamada Ltd. (Imported by: Valneva Canada, Inc.)	Sanofi Pasteur Limited
Biological Classification	Passive: Immune Globulin		
Indications for Provincially Funded Vaccine	**Post exposure prophylaxis:** • Must be considered for individuals of all ages if potential human exposure to rabies virus has occurred and should be initiated as soon as possible after the exposure. However, if indicated based on risk assessment, rabies post-exposure prophylaxis (PEP) should be offered to exposed individuals regardless of the time interval after exposure. o The animal species, the incident and the type of exposure must be considered as well as immunization status of the animal (if applicable) and presence of rabies in the area. • For further disease information, assessment of exposure and reporting requirements refer to Rabies Prevention and Control Manual Guidance for Public Health and Veterinary Professionals • The MOH/MOH designate within the AHS Zone will authorized the release of RIG or rabies vaccine for an individual. The Office of the Chief Medical Officer of Health (OCMOH) is available for consultation if desired by the MOH. **Notes:** • Each zone has been provided with a stock supply of RIG and rabies vaccine to initiate post exposure prophylaxis. See *Rabies Vaccine Biological Page #07.311 Appendix A* for detailed information on reporting of doses administered and process for ordering replacement vaccine. • Previous immunization (pre or post-exposure) does not eliminate the need for prompt PEP when a significant exposure occurs. It may eliminate the need for rabies immune globulin (RIG) and may reduce number of vaccine doses required for PEP. o Individuals who have completed appropriate rabies immunization and are known to have ever had an adequate antibody titre (rapid fluorescence focus inhibition test result of 0.5 IU/mL or greater) should not receive RIG. See Rabies Vaccine Biological Page #07.311 for definition of appropriate rabies immunization. • Follow-up of individuals from out of province requiring rabies PEP should be discussed with zone MOH/MOH designate and referred directly to AH Immunization Program. The AH Nurse Consultant will send a referral to the appropriate jurisdiction to ensure follow up is completed.		
Schedule	• Rabies immune globulin (RIG) should be administered concurrently with the first dose of rabies vaccine using separate syringe/needle and at a different anatomical site. **Notes:** • If RIG is not administered at the initiation of the rabies vaccine series (day 0), it can be administered up to and including day 7 after the first dose of rabies vaccine. • Additional doses may interfere with maximum immunity from the vaccine. RIG should be administered only one time during rabies PEP.		

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	• RIG is not indicated for individuals who have been appropriately immunized. See #07.311 Rabies Vaccine Biological Page. • RIG is recommended for those individuals who have not been appropriately immunized. See #07.311 Rabies Vaccine Biological Page. • For further follow up information refer to provincial guidelines (see link) Rabies Prevention and Control Manual Guidance for Public Health and Veterinary Professionals as well as zone processes.		
Preferred Use	There will be no preference indicated for the use of HyperRAB® or IMOGAM® or KamRAB® in specific age or risk groups. • All products are safe and immunogenic in all individuals. • Persons with medical contraindications should be offered the alternate product if supply is available.		
Dose	20 IU/kg (0.0665 mL/kg) of body weight **Note:** Concentration is 300 IU/mL • Rabies immune globulin is packaged as a 1 mL and 5 mL single use vials with 300 IU/mL • The recommended dose of RIG should not be exceeded because of possible interference of RIG with the immune response to rabies vaccine.	20 IU/kg (0.1333 mL/kg) of body weight. **Note:** Concentration is 150 IU/mL • Rabies immune globulin is packaged as 2 mL or 10 mL single use vials with 150 IU/mL • The recommended dose of RIG should not be exceeded because of possible interference of RIG with the immune response to rabies vaccine.	20 IU/kg (0.133 mL/kg) of body weight **Note:** Concentration is 150 IU/mL • Rabies immune globulin is packaged as a 2 mL vial, which contains a total of 300 IU (150 IU/mL). • The recommended dose of RIG should not be exceeded because of possible interference of RIG with the immune response to rabies vaccine.
Route	The most effective use of RIG is in the wound. Infiltration into and around the wound(s) or at the site of exposure. Remainder of the dose given IM. **Note:** • Wound infiltration is beyond the scope of practice for RNs, this procedure should be carried out by a physician. • If anatomically feasible, the full dose should be infiltrated in the wound and surrounding area by the physician. Any remaining volume should be injected intramuscularly at an anatomical site distant from the vaccine administration. • When more than one wound exists, each wound should be locally infiltrated with a portion of the RIG using a separate needle. o For HyperRAB® - if the wound covers a large area and the dose has insufficient volume to infiltrate the entire wound HyperRAB® may be diluted with an equal volume of dextrose, 5% (D5W) in water. Do not dilute with normal saline. o KamRAB® - RIG can be diluted twofold to threefold in a solution of 0.9% sodium chloride in order to provide the full amount of RIG required for thorough infiltration of all wounds.[6,8,11,12] o For IMOGAM® - the RIG can be diluted twofold to threefold in a solution of 0.9% sodium chloride in order to provide the full amount of RIG required for thorough infiltration of all wounds. • RIG should be infiltrated whenever possible with the following exceptions: o If the site of the wound/exposure is unknown, or o If it is not anatomically feasible, or o If the opportunity to provide RIG would otherwise be missed In these situations the entire dose of RIG should be administered intramuscularly.		

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Contraindications/ Precautions	**Contraindications:** • Individuals who have completed appropriate rabies immunization and are known to have ever had an adequate antibody titre (rapid fluorescence focus inhibition test result of 0.5 IU/mL or greater) should not receive RIG. **Precautions:** • RIG should not be administered later than day 7 after initiation of a vaccine series. • RIG should be given only one time during rabies PEP (not later than day 7 after the initiation of rabies vaccine series). Additional doses may interfere with maximum immunity from the vaccine. • Administer with caution to individuals with a history of prior systemic allergic reactions following the administration of human immune globulin preparations. • Individuals with IgA deficiency have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA. • No more than the recommended dose should be given (may partially suppress active production of antibody). • HyperRAB®, KamRAB® and IMOGAM® are made from human plasma. Products made from human plasma may contain infectious agents 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, testing for the presence of certain current viral infections and inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. o A signed *Consent for Treatment/Procedure* is required before administering immune globulin products.		
Possible Reactions	**Common:** • Pain or soreness, redness, induration at the injection site • Fever, headache, malaise **Rare:** • Bruising • Fatigue, dizziness, feeling faint • Myalgia, arthralgia • Nausea, abdominal pain • Upper respiratory tract infection • Blood in urine, white blood cells in urine • Sunburn • Angioneurotic edema, rash, nephrotic syndrome • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.		
Pregnancy	Pregnancy is not a contraindication to rabies PEP.		
Lactation	Breastfeeding is not a contraindication to rabies PEP.		
Composition	Each 1.0 mL contains: • 300 IU/mL rabies immune globulin (average potency value) • 15% to 18% protein solution • 0. 16 to 0.26 M glycine No preservative	Each 1.0 mL contains: • 150 IU/mL rabies immune globulin • Glycine • Water for Injection, • Sodium Hydroxide No preservative	Each 1.0 mL contains: • 100 to 180 mg human proteins containing (IgG-class) human rabies immunoglobulins with a minimum titre of 150 IU/mL • 22.5 mg glycine (stabilized with 0.3 M glycine)

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			• 1 mg sodium chloride • Up to 1 mL water • Sodium hydroxide or hydrochloric acid to adjust pH (6.8 ± 0.4) No preservative
Blood/Blood Products	Made from pooled human venous plasma		
Bovine/Porcine Products	• Bovine-derived materials are used in the early manufacturing processes but are not present in the final product. • Contains no porcine products.	• No bovine-derived materials are used in the manufacturing process. • Contains no porcine products.	• No bovine-derived materials are used in the manufacturing process. • Contains no porcine products.
Latex	HyperRAB® is not made with natural rubber latex.	The vial stopper is not made with natural rubber latex.	There is no latex in the vaccine or vaccine packaging.
Interchangeability	When at all possible the same product should be used.		
Administration with Other Products	• Administer the first dose of rabies vaccine and RIG at the same time for PEP whenever possible. • When administering RIG and rabies vaccine concurrently, use separate needles/syringes and different anatomical sites. • The recommended interval between RIG and subsequent immunization with MMR, MMR-Var or Varicella vaccine is 4 months. When it is necessary to administer RIG within 14 days after receiving MMR, MMR-Var, or Varicella vaccines, the vaccine should be repeated 4 months after the RIG administration. If RIG is given more than 14 days after the MMR, MMR-Var, or Varicella vaccines, the dose does not need to be repeated. • RIG cannot be given concurrently with live virus vaccines **Note:** • For further information, see #03.110 Standard for Recommended Immunization Schedules.		
Appearance	Clear to opalescent, colourless or pale yellow or pale brown solution.	Clear to opalescent liquid.	Colourless to light opalescent liquid
Storage	• Store at +2° to +8°C • Do not freeze • Do not use beyond the labeled expiry date • Store in original packaging when possible to protect from light		
Vaccine Code	RIG		
Antigen Code	RIG		
Licensed for	All ages		
Program Notes: • 1983 September: Introduced into the program.			
Related Resources: • Rabies Immune Globulin Information Sheet • **AH – 0005** Rabies Post-exposure Prophylaxis Report (July 2014)			

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