Rabies Immune Globulin (Human)

Implementation Date: May 1, 2020

Rationale for Update:

- Updated to incorporate new product KamRAB®.

<table>
<tr><td colspan="4">Please consult the Product Monograph[1,2,3] for further information about the vaccine.</td></tr>
<tr><td></td><td>IMOGAM® Rabies Pasteurized</td><td>KamRAB®</td><td>HYPERRAB®</td></tr>
<tr><td>Manufacturer</td><td>Sanofi Pasteur Limited</td><td>Kamada Ltd.
(Imported by: Valneva Canada, Inc.)</td><td>Grifols Therapeutics LLC. distributed by Grifols Canada Ltd.</td></tr>
<tr><td>Authorization and access</td><td colspan="3">Special authorization and access procedures must be followed.
See Rabies Post-exposure - Authorizing and Obtaining Rabies Post-exposure Biologicals.</td></tr>
<tr><td>Off-license use</td><td colspan="3">None</td></tr>
<tr><td>Indications for use of provincially funded vaccine rabies immune globulin</td><td colspan="3">Post-exposure: Rabies PEP must be considered 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 PEP should be offered to exposed individuals regardless of the time interval after exposure.[4]
For disease information, assessment of exposure and reporting requirements refer to Rabies Prevention and Control Manual Guidance for Public Health and Veterinary Professionals[5]
Note: Individuals from out of province requiring rabies PEP should be referred to the Alberta Health Immunization Program. The Nurse Consultant will send a referral to the appropriate jurisdiction to ensure follow-up is completed.</td></tr>
<tr><td>Dose</td><td>IMOGAM® Rabies Pasteurized</td><td>KamRAB®</td><td>HYPERRAB®</td></tr>
<tr><td></td><td colspan="2">Post-exposure:
20 IU/kg (0.133 mL/kg) of body weight [1,2]
Note: Concentration is 150 IU/mL[1,2]</td><td>Post-exposure:
20 IU/kg (0.0665 mL/kg) of body weight [3]
Note: Concentration is 300 IU/mL[3]</td></tr>
<tr><td></td><td colspan="3">Note: The dose of rabies immune globulin (RIG) should not be exceeded because of possible interference of RIG with the immune response to rabies vaccine.[4]</td></tr>
</table>

Route	**Post-exposure**: The most effective use of RIG is in the wound.[6,8] Infiltration into and around the wound(s) or at the site of exposure.[1,2,3,6] Remainder of the dose given IM.[1,2,3,4,7] **Notes**: • If anatomically feasible, the full dose should be infiltrated into the wound and surrounding area by a physician. Any remaining volume should be injected intramuscularly at an anatomical site distant from the vaccine administration.[1,2,3,4,7] • When more than one wound exists, each wound should be locally infiltrated with a portion of the RIG using a separate needle.[4] 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.[1] 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.[4,8,9,10] 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.[3] • RIG should be infiltrated whenever possible with the following exceptions:[7] o If the site of the wound/exposure is unknown,[4,7] or o If it is not anatomically feasible,[4,7] or o If the opportunity to provide RIG would otherwise be missed.[7] In these situations the entire dose should be administered intramuscularly.[4,7]
Schedule	**Post-exposure:** • RIG should be administered concurrently with the first dose of rabies vaccine using separate syringe/needle and at a different anatomical site.[4] **Notes**: • If RIG is not administered as recommended at the initiation of the post-exposure rabies vaccine series (day 0), it can be administered up to seven days after the first dose of vaccine is administered.[4] • Additional doses may interfere with maximum immunity from the vaccine.[11] RIG should be administered only one time during rabies PEP.[8,11] • RIG is not indicated for individuals who have been appropriately immunized. See Biological Products - Rabies Vaccine. • RIG is recommended for those individuals who have not been appropriately immunized.[4] See Biological Products - Rabies Vaccine. • The recommended interval between RIG and subsequent immunization with MMR, MMR-Var, or Varicella vaccines is four months.[4] • 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.[4] See Assessment Expected prior to Vaccine Administration – Guidelines for interval between immune globulin and live vaccines.

Contraindications	Individuals who have previously completed rabies immunization and are known to have an adequate antibody titre (rapid fluorescence focus inhibition test result of 0.5 IU/mL or greater) should not receive RIG.
Precautions	• Administer with caution to individuals with a history of prior systemic allergic reactions following the administration of human immune globulin preparations.[1,2,3] • 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.[1,2,3]
Possible reactions	See Product Monograph.
Pregnancy	Pregnancy is not a contraindication to rabies PEP.[1,2,3,4]
Lactation	Breastfeeding is not a contraindication to rabies PEP.[1,2,3,4]
Program Notes	• 1983 September – Introduced into program.

References

[1] Sanofi Pasteur Limited. (2015, December). Imogam® Rabies Pasteurized: Rabies immune globulin, pasteurized (human). *Product Monograph*.

[2.] Kamada Ltd. (2018 November 7). Rabies Immunoglobulin (Human). KamRAB®. *Product Monograph*.

[3] Grifols Therapeutics Inc. (2019, March 13). Rabies immune globulin (human): HyperRAB®. *Product Monograph*.

[4] National Advisory Committee on Immunization. (2018). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html

[5] Alberta Health. *Rabies Prevention and Control Manual: Guidance for Public Health and Veterinary Professionals.* https://open.alberta.ca/publications/9781460142639

[6] World Health Organization. (2018, April 20) Rabies vaccines: WHO position paper, weekly epidemiological record. No 16, 2018, 93, 201-220. Retrieved from: http://www.who.int/rabies/resources/who_wer9316/en/

[7] Alberta Advisory Committee on Immunization (AACI). (2019, January). Record of Decisions.

[8] World Health Organization (2018) Frequently asked questions about rabies for Clinicians. Retrieved from: http://www.who.int/rabies/Rabies_Clinicians_FAQs_21Sep2018.pdf?ua=1

[9] American Academy of Pediatrics. (2018) *Red book: 2018 Report of the Committee of Infectious Diseases (31st ed.).* Elk Grove Village, IL.

[10] Personal communication from Valneva regarding dilution or product. (2020 March 16).

[11] Grabenstein, J. D. (2012). *ImmunoFacts: Vaccines and Immunologic Drugs 2013*. St. Louis, MO: Wolters Kluwer Health.

