

Rabies Immune Globulin Provincial Shortage and Formulation Change

Update to York Region Health Care Providers as of August 19, 2019

Rabies Immune Globulin Provincial Shortage

The demand for rabies post-exposure prophylaxis (rPEP), which consists of rabies immune globulin (Rablg) and rabies vaccine, has risen sharply across Canada in recent weeks following media reports of a B.C man's death from rabies. This has resulted in Rablg shortages across Ontario and Canada and implementation of Rablg-sparing measures in several provinces. Ontario's Ministry of Health anticipates this Rablg shortage in Ontario may last until November 2019 before supply can be replenished by the manufacturers.

To help manage the shortage of Rablg, here are some helpful reminders when considering rPEP for your patient:

- rPEP should be given only if indicated by an evidence-based risk assessment.
- When notified of an animal exposure incident, York Region Public Health (YRPH) will conduct a risk assessment and share recommendations regarding the need for rPEP with the attending health care provider.
- For exposures where rPEP is administered, infiltrate Rablg around the wound(s) or exposure site(s). **If the entire Rablg dose anatomically cannot be infiltrated around the wound(s) or exposure site(s) – such as for a finger – the World Health Organization (WHO) no longer recommends injection of the remaining calculated Rablg dose intramuscularly (IM) at a site distant from the site of exposure.**
- **Based on this newer WHO position, and the current limited supply of Rablg, Ontario's Ministry of Health has implemented a Rablg-Sparing Protocol. Please see the attached Rablg-Sparing Protocol for more details and use it when administering rPEP.**
- For delicate/smaller anatomical sites (i.e. finger tips, hand, toes), based on the temporary Rablg-Sparing Protocol, health care providers are requested only to order sufficient Rablg to infiltrate around the wound(s) or exposure site(s).
- Attending health care providers ultimately decide whether rPEP will be administered.
- rPEP administration: Rablg administered on day 0 and rabies vaccine administered on days 0, 3, 7 and 14 for most individuals. Immunocompromised patients receive an extra dose of rabies vaccine on day 28.

Health Protection

17250 Young Street
Newmarket, Ontario L3Y 6Z1
1-800-361-5653
york.ca/rabies



Changes to Formulations of Rabies Immune Globulin

Effective immediately, Rablg will be available in a new formulation (1 mL) in addition to the 2 mL formulation currently in use. Health care providers requesting rPEP for persons not previously immunized against rabies will receive one of the following formulations of rabies immune globulin:

- HyperRAB®: 2 mL vials each containing a total of 300 IU (at a formulation of 150 IU/mL); or
- HyperRAB®: 1 mL vials each containing 300 IU (at a formulation of 300 IU/mL) **(NEW)**

What do you need to know about this Rablg formulation change?

- The number of International units (IU) of Rablg per vial (300 IU) does not differ between the formulations; only the volume in each formulation differs.
- Health care providers must confirm the formulation to be received from YRPH and calculate the dose of Rablg (20 IU/kg (or 9.09 IU/lb) body weight).
- A reference document to assist you with Rablg dose calculation accompanies this document; you can also call YRPH Health Connection at 1-800-361-5653 for assistance with dose calculation.
- Attending health care providers ultimately decide on the amount of Rablg required for their patient to be dispensed by public health.

How to contact York Region Public Health:

To discuss a potential animal exposure or rabies risk assessment, or if you have questions or requests for rPEP, call Health Connection at 1-800-361-5653 on weekdays between 8:30 am and 4:30 pm or at 1-888-335-0111 after hours and on weekends or holidays.

For more information related to rabies and rPEP:

Ontario. Ministry of Health and Long-Term Care. Management of Potential Rabies Exposures Guideline, 2019.

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Management of patients with suspected rabies exposure: Guidance for health care providers working with your local public health unit. 2017.

Ontario. Ministry of Health and Long-Term Care. Rabies Prevention and Control Protocol, 2019.

Weekly Epidemiological Record, 20 April 2018, vol. 93, 16 (pp. 201–220) Rabies vaccines: WHO position paper – April 2018. WHO Strategic Advisory Group of Experts (SAGE) on immunization.

Ministry of Health

Office of Chief Medical Officer of Health, Public Health
393 University Avenue, 21st Floor
Toronto ON M5G 2M2

Tel.: 416 212-3831
Fax: 416 325-8412

Ministère de la Santé

Bureau du médecin hygiéniste en chef, santé publique
393 avenue University, 21^e étage
Toronto ON M5G 2M2

Tél. : 416 212-3831
Télééc. : 416 325-8412

August 9, 2019

MEMORANDUM

TO: Medical Officers of Health and Associate Medical Officers of Health

RE: Rabies Immune Globulin-Sparing Measures

Dear Colleagues,

Due to the recent Canadian human rabies case from a bat exposure, the usage of rabies immune globulin (Rablg) has increased significantly, resulting in a limited supply of Rablg being available both within Ontario and across Canada. This situation of limited Rablg supply may continue until November 2019.

Boards of health are being asked to reinforce messaging to local physicians and health-care providers about the pending shortage of rabies biologicals in the province, and the importance of adhering to appropriate risk assessment recommendations provided by health units for potential human exposures to rabies to promote judicious use of the limited provincial supply.

In an effort to ensure Rablg availability going forward, a Rablg-sparing protocol has been developed (see attached). Please ensure that healthcare providers administering rabies post-exposure prophylaxis are aware of this revised protocol effective immediately.

Furthermore, Medical Officers of Health are encouraged to assess all cases where an exposure requiring rabies post-exposure prophylaxis involves a bite to a finger, or another anatomical location where an entire calculated dose of Rablg likely cannot be infiltrated around the wound, and consider dispensing a reduced number of vials of Rablg to ensure that unopened vials are not wasted unnecessarily once they leave the health unit.

Should you have any questions, please contact Infectious Disease Policy and Programs at IDPP@ontario.ca

Sincerely,



David C. Williams, MD, MHSc, FRCPC
Chief Medical Officer of Health

c: Dr. Peter Donnelly, President and CEO, Public Health Ontario

Attachment: Rabies Immune Globulin-Sparing Guidelines for Ontario

August 09, 2019

Rabies Immune Globulin–Sparing Guidelines for Ontario:

For cases where rabies post-exposure prophylaxis has been recommended

Due to a recent human case of rabies in Canada resulting from a bat exposure, there has been a significant increase in the use of rabies immune globulin (Rablg) both in Ontario and across Canada. As a result, the available supply of Rablg is currently limited.

The World Health Organization (WHO) no longer recommends injecting the remainder of the calculated Rablg (WHO uses the term RIG in their guidelines) dose IM at a site distant from the site of exposure.¹ Based on this newer WHO position and the current limited supply of Rablg, please follow the Rablg-sparing steps below when administering rabies post-exposure prophylaxis.

Rablg-Sparing Protocol

This protocol relates to the use of Rablg. Treatment of any wounds (thorough cleaning, flushing, antibiotics, analgesics, tetanus vaccination etc.) and the administration of rabies vaccines should follow normal protocols.²

1. Calculate the dose of Rablg (20 IU/kg body weight) and the number of vials required for this dose.
2. Draw up one vial at a time in order to save any unopened vials that you don't use.
3. Infiltrate as much of the calculated dose as possible around the wound(s) or site of exposure (if a bite or scratch is not evident).

Note: Infiltration of wounds with Rablg in some anatomical sites (finger tips) must be carried out with care in order to avoid increased pressure in the tissue compartment. When more than one wound exists, each wound should be locally infiltrated with a portion of the Rablg using a separate needle and syringe. In such instances, Rablg can be diluted twofold to threefold in a solution of 0.9% sodium chloride in order to provide the full amount of Rablg required for thorough infiltration of all wounds.²

4. If the entire calculated dose of Rablg cannot anatomically be infiltrated around the wound(s) or site of exposure, **do NOT give the remainder of the dose IM**. Save any unopened vials for use in another case.
5. For situations that are not clear, the attending healthcare provider makes the final decision regarding the administration of Rablg, along with input from the Medical Officer of Health.

¹Weekly Epidemiological Record, 20 April 2018, vol. 93, 16 (pp. 201–220) Rabies vaccines: WHO position paper – April 2018. WHO Strategic Advisory Group of Experts (SAGE) on immunization. Available from: <https://www.who.int/wer/2018/wer9316/en/>.

²Ontario Public Health Standards: Protocols and Guidelines. *Management of Potential Rabies Exposures Guidelines, 2019*. Available at: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/protocolsguidelines.aspx.

2019 CHANGES TO FORMULATIONS OF RABIG AVAILABLE IN ONTARIO

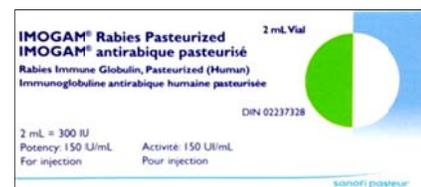
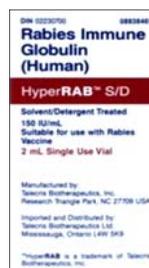
As of July 2019, Rabies Immune Globulin (RABIG) will be available in one of two formulations:

- 2 mL vials containing 150 IU/ml; or
- 1 mL vials containing 300 IU/ml.

Ensure that the appropriate formula, specific to the Rablg formulation provided by the health unit, is used to calculate the dose required for the individual to receive Rablg:

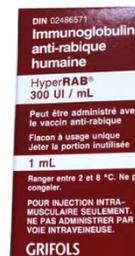
For 150 IU/ml Rablg in 2 ml vials:

- $20 \text{ IU/kg} \times (\text{client wt in kg}) \div 150 \text{ IU/mL} = \text{dose in mL}$
 $\text{dose in mL} \div 2 \text{ mL/vial} = \# \text{ of vials to order}$
- $9.09 \text{ IU/lb} \times (\text{client wt in lb}) \div 150 \text{ IU/mL} = \text{dose in mL}$
 $\text{dose in mL} \div 2 \text{ mL/vial} = \# \text{ of vials to order}$



For 300 IU/ml Rablg in 1 ml vials:

- $20 \text{ IU/kg} \times (\text{client wt in kg}) \div 300 \text{ IU/mL} = \text{dose in mL}$
 $\text{dose in mL} \div 1 \text{ mL/vial} = \# \text{ of vials to order}$
- $9.09 \text{ IU/lb} \times (\text{client wt in lb}) \div 300 \text{ IU/mL} = \text{dose in mL}$
 $\text{dose in mL} \div 1 \text{ mL/vial} = \# \text{ of vials to order}$



Important: The amount of Rablg administered may include the administration of only a portion of one of the vials ordered. For example, a patient that requires 7mL of Rablg should only have 3.5 vials administered, rather than 4 full vials, with the remainder of the Rablg in the 4th vial being discarded.

Note: While the dose in mL to be administered will be different depending on which formulation of Rablg is being used, the number of vials dispensed by the health unit will be the same.

If you have question please contact Health Connection at 1-800-361-5653 opt 4

Health Protection

1-800-361-5653 opt. 4
TTY 1-866-512-6228
york.ca/rabies

