Rabies Vaccine

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.311**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	March 1, 2013	**Revised**	January 31, 2025

	Imovax Rabies	**RabAvert**
Manufacturer	Sanofi Pasteur SA – distributed by Sanofi Pasteur Limited	GlaxoSmithKline Inc.
Classification	Inactivated	

Indications for Provincially Funded Vaccine	**Pre-exposure immunization:**
	• Rabies vaccine will be provided for the following high-risk occupational groups:
	  ○ Workers routinely caring for animals, including veterinarians, veterinary health technicians, veterinary assistants, Humane Society/SPCA workers, zoo workers and workers in animal shelters
	  ○ Animal research workers, including rabies laboratory workers and those in other laboratories working with rabies-prone species
	  ○ Animal control workers, including bylaw officers, and dog pound workers
	  ○ Wildlife workers, including fish and wildlife workers, foresters
	  ○ Students attending a post-secondary institution and enrolled in a veterinarian, veterinary health technician, or veterinary assistant program
	  ○ Spelunkers (cavers): Albertans involved in work-related spelunking.
	Note:
	• Volunteers, recreational spelunkers and those at risk due to international travel are not eligible to receive provincially funded rabies vaccine.
	• Employees under federal jurisdiction including the Canadian Food and Inspection Agency (CFIA) and Parks Canada are not eligible to receive provincially funded rabies vaccine.
	• Pre-exposure rabies vaccine must be ordered through Alberta Health (AH), Provincial Vaccine Depot (PVD) through your zone vaccine depot.
	• Book groups of six or more people to minimize vaccine wastage. When risk of exposure is high and immediate immunization is required, consult with your zone immunization contact. They will consult with AH before proceeding with a vaccine series using the IM route.	

	Post-exposure prophylaxis (PEP): • Must be considered for individuals of all ages if potential exposure to rabies virus has occurred. 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. • Pre-exposure rabies immunization does not eliminate the need for prompt post exposure prophylaxis (PEP) when a significant exposure occurs. It does eliminate the need for rabies immune globulin (RIG) and reduces the number of vaccine doses required for PEP. • Refer to Rabies prevention and control manual guidance for public health and veterinary professionals for risk assessment to determine if PEP is indicated. **Note:**	

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	• The Zone MOH/MOH designate will authorize the release of rabies immune globulin (RIG) or rabies vaccine. The Office of the Chief Medical Officer of Health (OCMOH) is available for consultation if desired by the MOH. • Each zone has been provided with a stock supply of RIG and rabies vaccine from AH PVD to initiate PEP. • Follow-up of individuals travelling out of province requiring continuation or completion of rabies PEP should be referred to the Provincial Immunization Team. The Provincial Immunization Team will coordinate a referral to the Alberta Health (AH) Immunization Program. The AH Nurse Consultant will send a referral to the appropriate jurisdiction to ensure follow up is completed. • Discuss follow-up of individuals who initiated rabies PEP out of province requiring completion of a rabies PEP vaccine series with the Zone MOH/MOH designate.	
Serology	**Pre-exposure:**	

	Primary series:
	• Rapid fluorescent-focus inhibition test (RFFIT) result of less than 0.5 IU/mL indicates the need for a reinforcing dose.
	• Offer a reinforcing dose of rabies vaccine to individuals with test results reported as 0.5 IU/mL up to and including 1 IU/mL who are at increased or continuing risk of rabies exposure. This is due to inherent imprecision in the RFFIT rabies assay.
	• When ID administration of the vaccine is used instead of IM, do serology at least 2 weeks after the third dose to ensure adequate protection.
	  ○ Offer a reinforcing dose using the ID route if protection is not adequate.
	  ○ Repeat serology at least 2 weeks after this reinforcing dose.
	  ○ Consult with Zone MOH/MOH designate if adequate protection is still not achieved.
	• Send individuals who are immunocompromised due to illness or immunosuppressive agents or taking chloroquine or hydroxychloroquine for serology 7 to 14 days after pre-exposure immunization series.
	  ○ Offer a second series of vaccine if an acceptable response is not achieved.
	  ○ Repeat serology at least 7 to 14 days after the second series of vaccine is complete.
	  ○ Consult with Zone MOH/MOH designate if adequate protection is still not achieved.
	Reinforcing doses:
	• Determine immunity every 2 years for individuals at continuing risk (occupational groups listed under indications) of rabies exposure.
	• Test research lab workers working with live rabies virus at risk of unapparent exposure for rabies immunity every 6 months.
	• Determine antibody levels before offering any reinforcing dose of vaccine. Offer rabies vaccine reinforcing dose if the RFFIT result is less than 0.5 IU/mL.
	• Offer a reinforcing dose of rabies vaccine to individuals with test results reported as 0.5 IU/mL up to and including 1 IU/mL who are at increased or continuing risk of rabies exposure.
	• When the reinforcing dose is given by ID administration repeat, serology at least 2 weeks after the dose to ensure adequate protection. Consult with Zone MOH/MOH designate if adequate protection is not achieved.	

	Post-exposure prophylaxis (PEP):	

	• Send individuals who are immunocompromised due to illness or immunosuppressive agents or taking chloroquine or hydroxychloroquine for serology 7 to 14 days after post-exposure immunization series.
	  ○ Offer a second series of vaccine if an acceptable response is not achieved.
	  ○ Repeat serology 7 to 14 days after the second series of vaccine is complete.	

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	• Consult with the Zone MOH/ MOH designate if a dose in the routine post-exposure prophylaxis schedule is missed as serology testing may be recommended. **Serology requisition** is located on the Alberta Health Services external webpage under Laboratory Services – Forms & Requisitions. Go to the Provincial Laboratory for Public Health (ProvLab) select Zoonotic Serology Requisition.	
Schedule	**Pre-exposure:**	

	Primary series (3 doses):
	• Dose 1 – day 0
	• Dose 2 – day 7
	• Dose 3 – day 21 to 28
	Reinforcing doses:
	• It is recommended that the following individuals receive reinforcing doses of vaccine based on determination of immunity and ongoing risk of exposure. See Serology Section for recommendations.
	• Every 6 months for research lab workers working with live rabies virus at risk of unapparent exposure
	• Every 2 years for individuals with continuing risk (occupational risk groups listed above).
	• Determine antibody levels before offering any reinforcing dose of vaccine.
	Note:
	• When ID administration of the vaccine is used, serology should be checked at least two weeks after completion of the vaccine series or after a reinforcing dose to ensure adequate protection.
	• Offer a reinforcing dose to individuals who have received an undocumented rabies immunization series and present with rabies serology indicating inadequate immunity.
	  ○ Send for serology at least two weeks after the reinforcing dose.
	  ○ If serology following the reinforcing dose indicates inadequate immunity, offer two more doses to complete a series.
	  ○ Consult with Zone MOH/ MOH designate if adequate protection is still not achieved.	

	Post-exposure prophylaxis (PEP):	

	Previously **unimmunized** individuals who are:
	Immunocompetent (4 doses)
	• **IM** – 1 mL each
	  ○ Dose 1 – day 0 (day 0 is the day the first dose is administered)
	  ○ Dose 2 – day 3
	  ○ Dose 3 – day 7
	  ○ Dose 4 – day 14
	OR
	• **ID** - 0.1 mL each at two anatomical sites (for a total of 0.2 mL)
	  ○ Dose 1 – day 0 (day 0 is the day the first dose is administered)
	  ○ Dose 2 – day 3
	  ○ Dose 3 – day 7
	  ○ Dose 4 – day 14
	Note:
	• ID administration is the preferred route of administration (unless contraindicated) when operationally feasible and clients can be clustered.
	• IM administration may be considered when Rabies PEP is being provided to one individual and using the ID route would create vaccine wastage.	

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	• Series may be completed using a mixed IM/ID schedule as long as the scheduling is maintained.
	
	Immunocompromised individuals (due to illness or immunosuppressive agents), or taking chloroquine or hydroxychloroquine (5 doses)
	• **IM** – 1 mL each
	  ○ Dose 1 – day 0 (day 0 is the day the first dose is administered)
	  ○ Dose 2 – day 3
	  ○ Dose 3 – day 7
	  ○ Dose 4 – day 14
	  ○ Dose 5 – day 28
	Note:
	• Administer RIG to previously unimmunized individuals on day 0 at the same time as dose 1 of rabies vaccine. Use a different anatomical site from the vaccine.
	
	Previously **appropriately immunized** individuals (2 doses)
	• IM – 1 mL each
	  ○ Dose 1 – day 0
	  ○ Dose 2 – day 3
	OR
	• ID - 0.1 mL each at two anatomical sites (for a total of 0.2 mL)
	Unless immunocompromised or taking chloroquine or hydroxychloroquine
	  ○ Dose 1 – day 0
	  ○ Dose 2 – day 3
	Note:
	• RIG should not be administered for persons who are appropriately immunized (see notes below for further details)
	• If the individual is immunocompromised or taking chloroquine or hydroxychloroquine administer 1 mL rabies vaccine IM.
	Note:
	Appropriate rabies immunization consists of:
	• Documentation of a complete series of pre or post exposure immunization with human diploid cell vaccine (HDCV) as in Imovax Rabies or purified chick embryo cell vaccine (PCECV) as in RabAvert.
	• Documentation of complete immunization series with:
	  ○ Other types of rabies vaccine **OR**
	  ○ HDCV or PCECV that follows unapproved schedules **OR**
	  ○ ID rabies series with HDCV or PCECV vaccine **AND**
	  ○ Serology demonstrating an antibody response (0.5 IU/mL or greater) following completion of the immunization series.
	• If vaccine other than HDCV or PCECV was used for pre-exposure immunization and the person's immune status is not known, initiate a full course of treatment, including RIG. A serum sample may be collected before the vaccine is administered, and if adequate protection is demonstrated, the vaccine series may be discontinued, provided at least two doses of vaccine have been administered.
	Recommendations for post-exposure series initiated in another country:
	• If the post-exposure series initiated is a World Health Organization (WHO) approved vaccine and schedule - complete the series in consultation with MOH/MOH designate.	

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	• WHO approved vaccines include cell culture vaccines such as PCECV, purified Vero cell rabies vaccine and HDCV, and duck embryo vaccine.
	• See attached links for additional information:
	  ○ WHO Expert Consultation on Rabies
	  ○ Committee to Advise on Tropical Medicine and Travel (CATMAT): Statements and publications - Canada.ca
	• For uncertain vaccines or unknown schedules, including no clear documentation, restart series and offer RIG in consultation with the MOH/MOH designate.
	General information related to PEP:
	• Adhere to rabies PEP vaccine schedules as closely as possible. It is essential that all recommended doses of vaccine be administered.
	  ○ It is critical that the **first 3 doses** be spaced according to the schedule.
	  ○ Prolonging the interval between doses may seriously delay achieving the protective antibody titres, with potentially fatal consequences.
	  ○ Consult the MOH if a dose in the routine PEP schedule is missed. Resume series as soon as possible. Follow the minimum intervals between doses. See Section 5 of the Standard for Recommended Immunization Schedules.
	• 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.
	• Send for serology to determine rabies antibody level following completion of PEP for individuals who are immunocompromised (due to illness or immunosuppressive agents) or those taking chloroquine or hydroxychloroquine. See serology section for more information.	

Preferred Use	None. • Both vaccines are safe and immunogenic in all individuals. • Offer individuals with medical contraindications to one product the alternate product if supply is available.	
Dose	**Pre-exposure:**	
	• 0.1 mL if given by the ID route **OR** • 1 mL if given by the IM route if ID administration is contraindicated.	
	Post-exposure:	
	• 0.1 mL ID each at two anatomical sites (for a total of 0.2 mL) **OR** • 1 mL given by the IM route (if ID administration is contraindicated or not operationally feasible).	
Route	**Pre-exposure:**	

	ID or IM (if the ID route is contraindicated):
	• **ID** injection (deltoid site) is the preferred route for healthy individuals for the primary series and reinforcing doses.
	Note:
	  ○ After reconstitution, the vaccine must be used as soon as possible and within 6 hours.
	  ○ Although rabies vaccine is not specifically licensed in Canada for ID administration, the World Health Organization (WHO) considers the ID regimen an acceptable alternative to IM administration as it uses less vaccine to produce a comparable degree of protection against rabies. Several Canadian provinces also provide pre-exposure rabies vaccine using the ID route for administration.
	• **IM** injection must be used for individuals who are immunocompromised due to illness or immunosuppressive agents, or those individuals who are taking chloroquine or	

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	hydroxychloroquine. The immune response to receiving vaccine ID may not be protective under these circumstances. ○ Never use the gluteal region for IM administration of rabies vaccine because it can result in a lower antibody response. ○ The deltoid area is the preferred site for adults and older children. For infants and younger children use the vastus lateralis.	
	Post-exposure prophylaxis (PEP):	
	ID or IM injection (if ID is contraindicated or not operationally feasible): • **ID** injection (deltoid site) ○ When administering the rabies vaccine by the ID route, a bleb must be present. If no bleb is present repeat the dose. Use a site a minimum of 1 inch away from the previous injection site. ○ After reconstitution, the vaccine must be used as soon as possible and within 6 hours. • **IM** injection must be used for individuals who are immunocompromised due to illness or immunosuppressive agents, or those individuals who are taking chloroquine or hydroxychloroquine. The immune response to ID vaccine may not be protective under these circumstances. ○ Never use the gluteal region for IM administration of rabies vaccine because it can result in a lower antibody response. ○ The deltoid area is the preferred site for PEP immunization of adults and older children. For infants and younger children use the vastus lateralis.	
Contraindications/ Precautions	**Contraindications:** • **Pre-exposure:** ○ Known severe hypersensitivity to any of the components of the vaccine or the vaccine container. ○ Anaphylaxis or other severe allergic reaction to a previous dose of vaccine containing rabies antigen. • **Post-exposure:** ○ There is no contraindication to rabies PEP because rabies disease is almost always fatal. Consult with the MOH/ MOH designate for individuals who are hypersensitive to the vaccine or any ingredients in the formulation. **Precautions:** • Give HDCV (Imovax Rabies) vaccine to individuals with a history of severe hypersensitivity reactions to egg or egg products. Do not give PCEVC (RabAvert). • Immunocompromised individuals may have a suboptimal response to rabies vaccine. • Immune suppressive agents or chloroquine and hydroxychloroquine should not be administered during post-exposure prophylaxis unless essential for the treatment of other conditions. Consult with Zone MOH/designate when providing PEP to immunocompromised clients.	
Possible Reactions	**Common:** • Pain, erythema, induration, bruising and itching at the injection site • Headache, nausea, abdominal pain, vomiting, diarrhea, decreased appetite, asthenia, myalgia, arthralgia, fatigue, malaise, fever, lymphadenopathy, rash and dizziness **Uncommon:** • Chills • Paresthesia • Allergic reaction with skin disorders or respiratory manifestations	

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	Rare: • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	• May use in pregnancy for PEP. • Consult with the Zone MOH/designate for pre-exposure immunization recommendation for a person who is pregnant. Pre-exposure immunization is generally delayed unless there is a substantial risk of exposure.	
Lactation	• May use for people who are lactating and feeding their milk to infants or children. • It is not known whether rabies vaccine or corresponding antibodies cross into breast milk.	
Composition	Each 1 mL dose of reconstituted vaccine contains: • 2.5 IU or more of rabies antigen • Less than 100 mg Human albumin • Less than 150 mcg Neomycin • 20 mcg phenol red indicator • Sterile water for injection (diluent) Contains no preservative or stabilizer	Each 1 mL of reconstituted vaccine contains: • 2.5 IU or more of rabies antigen • Less than or equal to 12 mg polygeline (processed bovine gelatin) • Less than or equal to 0.3 mg human serum albumin • 1 mg potassium L-glutamate • 0.3 mg disodium edetate) • Less than or equal to 3 ng ovalbumin (chicken protein) • Less than or equal to 10 mcg neomycin • Less than or equal to 200 ng chlortetracycline • Less than or equal to 20 ng amphotericin B • Traces of bovine serum • Sterile water (diluent) • Disodium edetate, Hydrogen chloride, polygeline, potassium-Lglutamate, sodium chloride, sucrose, trometamol (excipients) Contains no preservative
Blood/Blood Products	Each 1 mL dose of reconstituted vaccine contains less than 100 mg human albumin.	Each 1 mL dose of reconstituted vaccine contains less than 0.3 mg human serum albumin.
Bovine/Porcine Products	**Bovine Products:** • Bovine-derived products may be present in small amounts either as components of the culture media used to manufacture or as a component of the final product. **Porcine Products:** • Porcine-derived products are used as raw materials in the early stages of the manufacturing process.	**Bovine Products:** • Contains less than 12 mg polygeline (processed bovine gelatin). • Small quantities of bovine serum used in cell culture process. **Porcine Products:** • Does not contain porcine products.
Latex	Does not contain latex.	
Interchangeability	Complete the immunization series with the same product. However, if this is not possible, RabAvert and Imovax Rabies are considered interchangeable in terms of indications for use, immunogenicity, efficacy and safety.	

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Administration with Other Products	• Administer rabies vaccine and RIG concurrently when indicated for rabies PEP using separate needles/syringes and different anatomical sites.
	• May be given at the same time as other inactivated and live vaccines.
	  ○ Use a separate needle and syringe for each vaccine.
	  ○ The same limb may be used if necessary but use different injection sites on the limb.
	• Chloroquine and hydroxychloroquine and immunosuppressive agents may diminish the protective efficacy of the vaccine.	

Appearance	Freeze-dried vaccine is pinkish beige to orangey yellow. The diluent is a clear, colourless liquid. After reconstitution, the vaccine is clear or slightly opalescent red to purplish red suspension.	The white freeze-dried vaccine when reconstituted with the sterile water diluent dissolves to a clear to slightly opalescent, colourless to slightly pink solution.
Storage	Store at +2°C to +8°C. • Do not freeze. • Do not use beyond the labeled expiry date. • Store in original packaging to protect from light. • Use reconstituted vaccine as soon as possible and within 6 hours.	
Vaccine Code	RAB	
Antigen Code	RAB	
Licensed for	**Pre-exposure and post-exposure:** • 1 mL administered by IM route to all eligible individuals.	
Off-License Use	**Pre-exposure:** • 0.1 mL administered by ID route to eligible individuals. **Post-exposure:** • 0.1 mL administered by ID route to two anatomical sites to eligible individuals (for a total of 0.2 mL).	
Program Notes	• 1980 January 1: Rabies vaccine was introduced into program. • 1999 August: Imovax Rabies vaccine introduced. • 2005 June 1: RabAvert Rabies vaccine introduced. • 2013 August 29: Schedule change for Rabies PEP - introduced a 4 dose (versus 5 dose) post-exposure vaccine immunization schedule for immune competent individuals. • 2016 November 16: Recommendations included for post exposure series initiated in another country. • 2019 October: Alternate route and dose of post-exposure rabies vaccine. Vaccine to be administered ID (2 site 0.1 mL) when operationally feasible with the exception of immunocompromised individuals. • 2022 February 28: Clarified recommendation for individuals being assessed for pre-exposure rabies vaccine reporting undocumented rabies immunization series. • 2025 January 31: Updated to specify that workers in animal shelters are eligible for pre-exposure vaccine.	
Related Resources	• Rabies Vaccine Information Sheet • RabAvert Vaccine Instructions for Reconstitution https://www.drugs.com/dosage/rabavert.html	

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