Rabies Vaccine for PRE-EXPOSURE Prophylaxis

IMOVAX® Rabies Supplier: Sanofi Pasteur Limited
RabAvert® Supplier: GlaxoSmithKline Inc.

INDICATIONS:
Recommended and provided free to BC students attending a Canadian Veterinary College or Animal Health Technology Training Centre. These are considered to be low risk if in BC (see SEROLOGICAL TESTING).

Recommended but not provided free to the following persons at risk of contact with the rabies virus:

- **High Risk:** Rabies research laboratory workers, rabies biologicals production workers, bat biologists.
- **Moderate Risk:** Rabies diagnostic laboratory workers and spelunkers. Veterinarians and staff, animal control workers, wildlife biologists and wildlife workers in rabies enzootic areas. Hunters and trappers in high risk areas such as the far north.
- **Low Risk:** Veterinarians and staff, animal control and wildlife workers in areas of low rabies enzooticity. Children and travelers visiting foreign enzootic areas for 1 month or more. Travelers to foreign epizootic areas, trekking/hiking for any length of time, and far from a major medical centre.

DOSES AND SCHEDULE: \(^A\)

Immunocompetent individuals 18 years of age and older can be immunized using either the intradermal (ID) or intramuscular (IM) regimen. Immunocompromised individuals, children less than 18 years of age, and those on chloroquine or hydroxychloroquine, or planning to start chloroquine or hydroxychloroquine within a month of series completion, should be immunized using the IM regimen.

**INTRADERMAL ADMINISTRATION:** 2 doses of two-site ID administration (see ADMINISTRATION), given as 0.1 mL/site (total 0.2 mL) on each of days 0 and 7. (See SEROLOGICAL TESTING for additional recommendations following vaccine series completion).

**INTRAMUSCULAR ADMINISTRATION:** 3 doses given as 1.0 mL IM (2.5 IU) at 0, 7 and 21-28 days.

**ADMINISTRATION:**

- Both vaccines need to be reconstituted. Use the diluent provided with the vaccine. Following reconstitution IMOVAX® Rabies is a clear or slightly opalescent red to purplish red suspension while RabAvert® is a clear to slightly opalescent colorless to slightly pink solution.
- Neither vaccine contains any preservative and should be used immediately after reconstitution or discarded. However, when one vial is being used for multiple ID doses, the reconstituted vaccine can be used for up to 6 hours if stored at +2°C to +8°C.

\(^A\) If possible the series should be completed with the same product. If not feasible, IMOVAX® Rabies and RabAvert® are interchangeable in terms of indications for use, immunogenicity, efficacy, and safety.
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ADMINISTRATION (continued):

- Two-site ID administration of rabies vaccine:
  - The preferred site for ID administration of rabies vaccine is the deltoid area of the arms; alternatively the anterolateral area of the thighs and suprascapular areas can be used.
  - When given by the Two-site ID route, rabies vaccine should be given using 2 separate sites/limbs (refer to Appendix B – Administration of Biological Products, section 14.8.2 Intradermal (ID) Injection Route)
  - Administer rabies vaccine as 2 separate ID injections of 0.1 mL/site for a total of 0.2 mL at each visit.
  - For ID administration of rabies vaccine, a white elevated wheal (bleb) ≥5 mm in size should appear. If an elevated wheal sized at least 5 mm does not appear, repeat the procedure using an alternate site. For further information on ID administration, see Appendix B – Administration of Biological Products.
- Administer the entire contents of the reconstituted vaccine when administered IM.

SEROLOGICAL TESTING AND BOOSTER DOSES: ^

ID regimen: Serological confirmation of immunity is recommended 2 weeks following completion of the 2-dose ID regimen. A booster dose should be provided if antibody level is below 0.5 IU/mL.

IM and ID regimens:

- High Risk: Test clients every 6 months and boost when level falls below 0.5 IU/mL.
- Moderate Risk: Test clients every 2 years and boost when level falls below 0.5 IU/mL.
- Low Risk: Administer booster doses only following a subsequent exposure or as determined by post-exposure serology.

All booster doses should be provided as 1.0 mL IM, if required.

CONTRAINDICATIONS:

- History of anaphylactic reaction to a previous dose of rabies vaccine or any component of the vaccine. Note that the vaccine components differ for the two products (see PRODUCT COMPONENTS) and those with severe hypersensitivity to eggs should be immunized with IMOVAX® Rabies.
- Severe allergic or neuropathic reactions during the course of a rabies vaccine pre-exposure series warrant discontinuation of the series. The benefit versus risk of rabies vaccine receipt in the post-exposure context can be considered if a future rabies exposure occurs.

^A Draw serum sample and submit with requisition to BCCDC Public Health Laboratory (PHL) (http://www.elabhandbook.info/PHSA/Default.aspx). Under “Viruses”, check “Other” and add “rabies titre”. An acceptable (seroprotective) antibody level is ≥ 0.5 IU/mL. Testing is conducted by the National Microbiology Laboratory. Results are available from BCCDC PHL (telephone: 1-877-747-2522).
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PRODUCT COMPONENTS:
IMOVAX® Rabies (Human Diploid Cell Vaccine or HDCV):
Potential allergens: neomycin, phenol red.
Other components: human albumin.

RabAvert® (Purified Chick Embryo Cell Vaccine or PCECV):
Potential allergens: polygeline (processed bovine gelatin), ovalbumin, neomycin, chlortetracycline, amphotericin B.
Other components: human serum albumin, potassium L-glutamate, sodium edetate, sucrose, trometamol, hydrogen chloride.

PRECAUTIONS:
• The intradermal route should not be used for immunocompromised individuals, children less than 18 years of age or those on chloroquine or hydroxychloroquine, or planning to start chloroquine or hydroxychloroquine within a month of series completion.
• Persons receiving high doses of steroids or immunocompromised due to other reasons should have serological testing for rabies antibody 7-14 days after completion of an IM rabies vaccine series to ensure an adequate response has developed.

SPECIAL CONSIDERATIONS:
Not applicable.

ADVERSE EVENTS:
IMOVAX® Rabies:
Local: pain, erythema, swelling, pruritus, induration.
Systemic: headache, nausea, abdominal pain, myalgia, arthralgia, malaise, fever, dizziness.

RabAvert®:
Local: pain, swelling, erythema, induration.
Systemic: malaise, myalgia, arthralgia, headache, fever, fatigue, lymphadenopathy, nausea, rash.

While earlier rabies vaccines (Semple and SMB rabies vaccine) were associated with Guillain-Barré Syndrome, the occurrence of this syndrome following receipt of the vaccines currently used in North America is not above background rates.