

## Protocol for Rabies Vaccines (IMOVAX®, RabAvert®)

### 1. What's New

- A. Updated pre-exposure prophylaxis to the currently recommended 2-dose regimen for adults.

### 2. Immunization Protocol

- A. Administer a 1.0-mL dose, IM, of rabies vaccine according to the appropriate schedule and indication.
- B. If administering post-exposure prophylaxis, assess patient's tetanus vaccination status and co-administer, if indicated.

### 3. Vaccine Schedule

#### A. Pre-exposure prophylaxis<sup>3</sup>

Rabies Vaccine (IMOVAX®, RabAvert®) <sup>1,2</sup> Dose and Route - 1.0-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	≥18 years	Day 0
2		Day 7
Booster		See section 5, recommendations for use.

Rabies Vaccine (IMOVAX®, RabAvert®) <sup>1,2</sup> Dose and Route - 1.0-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	7-17 years	Day 0
2		Day 7
3		Day 21-28
Booster		See section 5, recommendations for use.

#### B. Post-exposure prophylaxis – unvaccinated person<sup>3</sup>

Rabies Vaccine (IMOVAX®, RabAvert®) <sup>1,2</sup> Dose and Route - 1.0-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	≥7 years	Day 0
2		Day 3
3		Day 7
4		Day 14
5*		Day 28

\* Necessary only for patients who are immunocompromised.

#### C. Post-exposure prophylaxis – previously vaccinated person<sup>3</sup>

Rabies Vaccine (IMOVAX®, RabAvert®) <sup>1,2</sup> Dose and Route - 1.0-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	≥7 years	Day 0
2		Day 3

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**4. Licensed Vaccines**

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
IMOVAX® <sup>1</sup>	Rabies	Single-dose vial of freeze-dried vaccine and diluent in a prefilled syringe	Licensed for all ages	No
RabAvert® <sup>2</sup>				

**5. Recommendations for Use**

A. Pre-exposure for high-risk persons.<sup>3</sup>

Risk Category	Who This Typically Affects	Recommendations
Category 1 <i>Highest Risk</i>	Laboratory workers handling live or concentrated rabies virus	2-dose pre-exposure prophylaxis. Check titer every 6 months; booster if titer <0.5 units/mL
Category 2	People frequently handling bats, having contact with bats, or entering high-density bat environments. People performing animal necropsies.	2-dose pre-exposure prophylaxis. Check titer every 2 years; booster if titer <0.5 units/mL
Category 3	People who interact with animals that could be rabid (other than bats). Risk lasts longer than 3 years after receiving pre-exposure prophylaxis.  This group includes most: - Veterinarians - Veterinary technicians - Animal control officers - Wildlife biologists - Wildlife rehabilitators - Trappers - Spelunkers (cave explorers)	2-dose pre-exposure prophylaxis, <b>plus:</b>  Check titer once after 1 to 3 years After completion of 2 dose primary series of pre-exposure prophylaxis; booster if titer <0.5 units/mL  <b>OR</b>  1 dose booster between 21 days and 3 years following completion of 2 dose primary series pre-exposure prophylaxis
Category 4	Same risk factors as category 3 but at risk for less than 3 years after receiving pre-exposure prophylaxis.  This group includes International travelers to endemic or high-risk countries	2 dose pre-exposure prophylaxis. No titer recommended
Category 5 <i>Lowest Risk</i>	General U.S. population	None

B. Pre-exposure prophylaxis for persons with altered immunocompetence.<sup>3</sup> For persons with altered immunity, the same series is recommended, but a titer is needed after completion

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of the vaccine series; a rabies antibody titer no sooner than 1 week after completion of the series (but ideally 2-3 weeks after it) should be  $\geq 0.5$  units/mL. If it is not, an additional dose should be administered followed by another titer check. If two such additional doses fail to achieve the minimum acceptable antibody titer, public health authorities should be consulted for case-specific guidance.

- C. Routine serologic testing for rabies virus neutralizing antibody: Is not necessary for high-risk persons working in areas where rabies is uncommon to rare (infrequent exposure group). If these persons are subsequently exposed, they will require post-exposure prophylaxis for a previously vaccinated person.
- D. Post-exposure treatment:<sup>4</sup> Bite from a dog, cat, or ferret. If healthy and available for observation, hold prophylaxis unless clinical signs of rabies develop. If animal is unavailable, consult with public health officials.

### 6. Contraindications

- A. Pre-exposure Prophylaxis: Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.<sup>3</sup>

Vaccine	Contains
IMOVAX <sup>®1</sup>	Human albumin, neomycin sulfate, phenol red, betapropiolactone.
RabAvert <sup>®2</sup>	Chicken protein, polygeline (processed bovine gelatin), human serum albumin, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B.

- B. Post-exposure Prophylaxis: Since rabies is almost always fatal, there are no contraindications to vaccination for post-exposure prophylaxis, including pregnancy.<sup>4</sup>

### 7. Warnings and Precautions<sup>3-5</sup>

- A. Immunosuppression: Persons with immunosuppression may be administered pre-exposure prophylaxis with the understanding that the immune response may be inadequate. Patients who are immunosuppressed by disease or medication should postpone pre-exposure prophylaxis and consider avoiding activities for which pre-exposure prophylaxis is indicated. When this is not possible, post-vaccination virus neutralizing antibodies should be checked. A patient who fails to seroconvert after the third dose should be managed in consultation with their physician and the Oregon Acute and Communicable Disease Section [ohd.acdp@dhsosha.state.or.us](mailto:ohd.acdp@dhsosha.state.or.us).
- B. Pregnancy: Pregnancy or breastfeeding is not a contraindication for postexposure prophylaxis. If the exposure risk is substantial, pre-exposure prophylaxis may be indicated during pregnancy. Certain studies have indicated no increased incidence of abortion, premature births, or fetal abnormalities associated with rabies vaccination. Rabies exposure or the diagnosis of rabies in the mother should not be regarded as reasons to terminate the pregnancy.
- C. Allergies: Persons who have a history of serious hypersensitivity to components of rabies vaccine or to other vaccines with components that are also present in rabies vaccine should be revaccinated with caution.

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- a. RabAvert® is produced in chick embryo cell culture. Persons with a history of serious allergic reaction to egg ingestion should be vaccinated with IMOVAX® or if unavailable, RabAvert® should be used with caution.
- b. IMOVAX® is produced in human diploid cells.

### 8. Other Considerations<sup>5</sup>

- A. For most persons, routine serological testing after pre-exposure or postexposure prophylaxis to document seroconversion is not necessary unless:
  - a. the person is immunosuppressed
  - b. significant deviations of the prophylaxis schedule have occurred
  - c. the patient received vaccination internationally with a product of questionable quality
  - d. the person's antibody status is being monitored routinely due to occupational exposure to rabies virus

### 9. Side Effects and Adverse Reactions

- A. Once initiated, rabies prophylaxis should not be interrupted or discontinued because of local or mild systemic adverse reactions to rabies vaccine. Usually, such reactions can be successfully managed with anti-inflammatory, antihistaminic, and antipyretic agents.<sup>1</sup>

Adverse Event	Frequency
Injection site events (pain)	Up to 84%
Injection site events (itching, redness, swelling)	Up to 45%
Systemic events (malaise, headache, dizziness, myalgia)	Up to 30%

### 10. Storage and Handling

- A. Store medications according to OAR 855-041-1036.

Vaccine	Temperature	Storage Issues	Notes
IMOVAX® <sup>1</sup> and RabAvert® <sup>2</sup>	2° to 8°C (36° to 46°F)	Do not freeze	Administer immediately after reconstitution.

### 11. References

1. IMOVAX®. Package insert. Swiftwater, PA: Sanofi Pasteur SA; Updated October 2019. <https://www.fda.gov/media/75709/download>. Accessed April 13, 2023.
2. RabAvert®. Package insert. Philadelphia, PA: GlaxoSmithKline; Updated 2018. <https://www.fda.gov/media/83874/download>. Accessed 13 April 2023.
3. Use of a Modified Preexposure Prophylaxis Vaccination Schedule to Prevent Human Rabies: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR 2022;71(18) 619-627. Available at: <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7118a2-H.pdf>. Accessed 13 April 2023.
4. Use of a Reduced (4-Dose) Vaccine Schedule for Postexposure Prophylaxis to Prevent Human Rabies. MMWR 2010; 59(02) 1-9. Available at: <https://www.cdc.gov/mmwr/pdf/rr/rr5902.pdf>. Accessed 13 April 2023.

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5. Human Rabies Prevention—United States, 2008. MMWR 2008; 57(03). Available at: <https://www.cdc.gov/mmwr/PDF/rr/rr5703.pdf>. Accessed 13 April 2023.

**12. Appendix**

- A. N/A

PROPOSED