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

#### **INDICATIONS:**

- Post-Exposure Prophylaxis (PEP) as determined by Medical Health Officer (MHO).
- If a rabies vaccine series has been started or completed elsewhere and it was **not** given in accordance with current WHO standards, administer another full course of rabies vaccine. See Communicable Disease Control Manual, Chapter 1: Rabies, Section 4.2.1.

#### DOSES AND SCHEDULE: A

Unimmunized immunocompetent individuals can be immunized using either the intradermal (ID) or intramuscular (IM) regimen. Immunocompromised individuals, those on chloroquine or hydroxychloroquine, and those who have been previously immunized should be immunized using the IM regimen.

If necessary, the route of administration can be changed once within the series. When switching the route, a fourth dose of vaccine should be provided on or after day 14.

#### INTRADERMAL ADMINISTRATION

#### Unimmunized immunocompetent individuals:

#### 3-dose schedule:

- Dose 1: Two-site ID administration (see <u>ADMINISTRATION</u>), given as 0.1 mL/site (total of 0.2 mL) on day 0 as soon as possible after exposure along with rabies immune globulin (Rablg) (see <u>Part 4 Biological Products</u>, Immune globulins, Rabies Immune Globulin)
- Doses 2 and 3: Two-site ID administration, given as 0.1 mL/site (total of 0.2 mL) on each of days 3 and 7

#### INTRAMUSCULAR ADMINISTRATION

#### Unimmunized immunocompetent individuals:

#### 4-dose schedule:

- Dose 1: Give 1 mL IM on day 0 as soon as possible after exposure along with rabies immune globulin (Rablg) (see Part 4 – Biological Products, Immune globulins, Rabies Immune Globulin)
- Doses 2 through 4: Give as 1 mL IM on days 3, 7, and 14

# Unimmunized immunocompromised persons and those on chloroquine or hydroxychloroquine:

#### 5-dose schedule:

- Dose 1: Give 1 mL **IM** on day 0 as soon as possible after exposure along with **Rabig** (see Part 4 Biological Products, Immune globulins, Rabies Immune Globulin)
- Doses 2 through 5: Give 1 mL IM on days 3, 7, 14, and 28

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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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#### **DOSES AND SCHEDULE (continued):**

Individuals previously immunized with a full course of documented rabies pre or post-exposure vaccine using a WHO approved rabies vaccine and schedule (see Communicable Disease Control Manual, Chapter 1: Rabies, Section 4.5) or those with prior documented anti-rabies antibody level of ≥ 0.5 IU/mL:

#### 2-dose schedule:

- Do not give Rablg
- Dose 1: Give 1 mL IM on day 0 as soon as possible after exposure
- Dose 2: Give 1 mL IM on day 3

#### RPEP started in another country:

RPEP received in another country may or may not be adequate. In determining the validity of Rablg or rabies vaccine administered overseas, a case-by-case assessment must be made. For guidelines on assessment and continuation of RPEP started in another country, see Communicable Disease Control Manual, Chapter 1, Rabies: Section 4.2.1.

#### ADMINISTRATION:

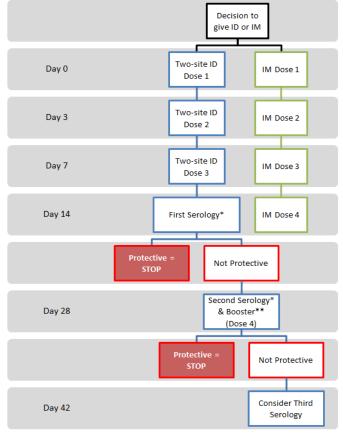
- Both vaccines need to be reconstituted. Use the diluent provided with the vaccine. Following
  reconstitution IMOVAX® Rabies is a clear or slightly opalescent red to purplish red
  suspension while RabAvert® is a clear to slightly opalescent colorless to slightly pink
  solution.
- Neither vaccine 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.
- 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 regimen, rabies vaccine should be given using 2 separate sites/limbs (refer to <u>Appendix B – Administration of Biological Products</u>, 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.
  - o 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 <u>Appendix B – Administration of Biological Products</u>.
- Administer the entire contents of the reconstituted vaccine when administered IM.
- Rabies vaccine and Rablg must **not** be administered in the same anatomical site. Use separate needles and syringes for each product.

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#### SEROLOGICAL TESTING AND RE-VACCINATION: A

#### Unimmunized immunocompetent individuals immunized via the ID regimen:

Serological confirmation of immunity is recommended following completion of the rabies vaccine series as follows:



<sup>\*</sup> Use the Zoonotics Diseases & Emerging Pathogens Requisition for the BCCDC Rabies Dose Study

**Figure 1**: Decision-tree and schedule for obtaining serology following three-dose intradermal administration of rabies vaccine for post-exposure prophylaxis of immunocompetent individuals. **In the event that serology does not demonstrate protection, the booster dose (dose 4) should be given using the Two-site ID regimen.** Serology is not required for a four-dose IM vaccine series.

#### **Unimmunized immunocompromised individuals:**

Serological confirmation of immunity is recommended 7-14 days following completion of the rabies vaccine series for those on high doses of steroids or immunosuppressed at the time of

<sup>\*\*</sup> Ensure serology is obtained prior to administration of the booster dose

<sup>&</sup>lt;sup>A</sup> An acceptable (seroprotective) antibody level is ≥ 0.5 IU/mL. Testing is conducted by the National Microbiology Laboratory. Results are available from the BCCDC Public Health Laboratory (PHL) at: 1-877-747-2522.

# Rabies Vaccine for POST-EXPOSURE Prophylaxis IMOVAX® Rabies RabAvert® Supplier: GlaxoSmithKline Inc.

immunization. A If the rabies antibody titre is below 0.5 IU/mL, a 2<sup>nd</sup> series of rabies vaccine should be given **IM**. If the titre remains below 0.5 IU/mL, the Medical Health Officer should be consulted for a risk assessment for further management.

#### **CONTRAINDICATIONS:**

- 1. There are **no** contraindications to rabies vaccine given for post-exposure purposes.
- 2. Severe allergic or neuroparalytic reactions during the course of a rabies vaccine series pose a serious dilemma. The risk of exposure to rabies must be carefully considered before a decision is made to discontinue rabies vaccine.

#### 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, disodium edetate, sucrose, trometamol, hydrogen chloride.

#### PRECAUTIONS:

Administer vaccine in an emergency room setting if history of an anaphylactic reaction to a
previous dose of rabies vaccine or to any of the components of the vaccine.

#### SPECIAL CONSIDERATIONS:

• If another vaccine (e.g., tetanus-containing vaccine) is being administered in the same limb as a dose of rabies vaccine, a separation of 2.5 cm (1 inch) between the vaccines is preferable so that local reactions are unlikely to overlap.

#### **ADVERSE EVENTS:**

IMOVAX® Rabies:

**Local:** pain, erythema, swelling, pruritus, induration.

Systemic: headache, nausea, abdominal pain, myalgia, arthralgia, malaise, fever, dizziness.

<sup>&</sup>lt;sup>A</sup> Use the requisition within the <u>eLab Handbook</u> to send to BCCDC PHL. Under "Viruses", check "Other" and add "rabies titre".

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#### **ADVERSE EVENTS (continued):**

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.