PART III: CONSUMER INFORMATION

RABAVERT
Rabies vaccine

This leaflet is part III of a three-part "Product Monograph" published when RABAVERT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RABAVERT. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is used for:

RABAVERT is indicated for:

- Pre-exposure vaccination, in both primary series and booster doses against rabies in all age groups.
- Post-exposure prophylaxis against rabies in all age groups.

What it does:
Intramuscular injection of RABAVERT induces lymphocytes to produce virus neutralizing antibodies that provide adequate protection against rabies virus.

When it should not be used:
In view of the almost invariably fatal outcome of rabies, there is no contraindication to post-exposure prophylaxis, including pregnancy.

History of anaphylaxis to the vaccine or any of the vaccine components, including the container, constitutes a contraindication to pre-exposure vaccination with this vaccine.

If you have an acute infection. The presence of a minor infection, such as a cold, should not require postponement of the pre-exposure vaccination, but talk to your doctor or nurse first.

What the medicinal ingredient is:
Rabies vaccine

What the nonmedicinal ingredients are:
Disodium edetate, hydrogen chloride, polygeline, potassium-L-glutamate, sodium chloride, sucrose, trometamol, water for injection. Residues from the manufacturing process: Amphotericin B, chlortetracycline, human serum albumin, neomycin, and ovalbumin.

What dosage forms it comes in:
RABAVERT is available as:
1 vial of lyophilized powder containing a single dose; and,
1 disposable pre-filled syringe of Sterile Diluent for RABAVERT (1 mL), with needles.

RABAVERT has at least 2.5 IU of rabies antigen.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Anaphylaxis and neuroparalytic events such as encephalitis, transient paralysis and Guillain-Barré-Syndrome, have been reported to be temporally associated with the use of RABAVERT. A patient's risk of developing rabies must be carefully considered, however, before deciding to discontinue immunization.

RABAVERT MUST NOT BE USED SUBCUTANEOUSLY AND SHOULD NOT BE USED INTRADERMALLY.

DO NOT INJECT INTRAVASCULARLY.

BEFORE you use RABAVERT talk to your physician or pharmacist if:

- You are under radiation therapy, antimalarials, corticosteroids, or other immunosuppressive agents.
- You are a person with immunosuppressive illnesses.
- You are allergic to this drug or its ingredients or components of the container.
- You have fainted with a previous injection. Fainting can occur following, or even before, any needle injection.
- You are or think you may be pregnant, you may still be given rabies vaccine if you have had, or are likely to have had, contact with the virus. If the risk

of contact with the virus is thought to be considerable, your doctor will advise you whether to have rabies vaccine now or to wait.
- You are breastfeeding. You can receive RABAVERT if the risk of contact with the virus is thought to be considerable. Your doctor will advise you.

As with all vaccines, RABAVERT may not fully protect all people who are vaccinated.

INTERACTIONS WITH THIS VACCINE

Drugs that may interact with RABAVERT include:
- Antimalarials
- Corticosteroids
- Immunosuppressive agents

RABAVERT can be given at the same time as other vaccines. A different injection site will be used for each type of vaccine.

You may also need to be given an injection of antibodies against rabies (called "rabies immunoglobulin"). If so, the rabies immunoglobulin injection will be given in different limbs.

PROPER USE OF THIS VACCINE

Usual dose:
A. Primary Immunization (Pre-exposure vaccination)

Three intramuscular injections of 1.0 mL each:
One injection on each of **Days 0, 7, and 21 (or 28)**

B. Booster Immunization

The individual booster dose is 1 mL, given intramuscularly.

C. Post-Exposure Prophylaxis

A complete course of immunization consists of a total of 5 injections of 1 mL each:
One injection on each of **Days 0, 3, 7, 14 and 28**
In conjunction with the administration of rabies immunoglobulin (RIG) on Day 0.

D. Post-Exposure Prophylaxis of Previously Immunized Persons

When rabies exposure occurs in a previously vaccinated person, then that person should receive two IM (deltoid) doses (1.0 mL each) of RABAVERT:
One dose immediately and one 3 days later.
Human Rabies Immunoglobulin (RIG) should not be given in these cases.

Missed Dose:
Please refer to your physician in case of a missed vaccination.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects reported can be:
- Very common (these may affect more than 1 in 10 people);
- Common (these may affect up to 1 in 10 people);
- Uncommon (these may affect up to 1 in 100 people);
- Rare (these may affect up to 1 in 1,000 people); or,
- Very rare (these may affect less than 1 in 10,000 people).

In very rare cases, neurological events such as those in the Serious Warnings and Precautions section above and other severe conditions affecting the brain and nerves have been reported in temporal association with administration of RABAVERT. Consult your physician if you experience any of these mentioned cases.

Your risk of developing rabies must be carefully considered, however, before deciding to discontinue immunization.

The most commonly occurring adverse reactions are injection-site reactions - such as swelling and pain; flu-like symptoms - such as fatigue, fever, headache, dizziness, weakness, and rash, that may also be red, lumpy, itchy (very common); injection-site redness, abdominal pain, lymph node swelling, muscle pain and general discomfort, joint pain, nausea, vomiting, diarrhea, and decreased appetite (common).

In rare cases, chills and sweating, circulatory reactions – such as hot flush - visual disturbance, tingling or numbness of skin, pain in limbs, feeling faint, fainting, and hypersensitivity have been reported.

Serious allergic reactions are rare after receiving a vaccine. These reactions may include:
• difficulty in breathing,
• blue discolouration of the tongue or lips,
• swelling of the face and neck or elsewhere
• low blood pressure causing collapse and shock.
When these signs or symptoms occur, they usually develop very quickly after the injection is given; consult a doctor immediately.

Once initiated, rabies prophylaxis should not be interrupted or discontinued because of local or mild general adverse reactions to rabies vaccine. Usually such reactions subside within a few days and may be successfully managed with anti-inflammatory and fever reducing agents.

This is not a complete list of side effects. For any unexpected effects while taking RABAVERT, *contact your physician or pharmacist.*

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:
If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:
Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

By toll-free telephone: 866-844-0018
By toll-free fax: 866-844-5931
By email: caefi@phac-aspc.gc.ca
At the following website:
http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php

By regular mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
Ottawa, Ontario
K1A 0K9 Address Locator 6502A

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

HOW TO STORE IT

RABAVERT should be stored protected from light at 2°C to 8°C. After reconstitution, the vaccine is to be used immediately. The vaccine may not be used after the expiration date given on package and container.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
www.valneva.ca

or by contacting the distributor:

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