PART III: CONSUMER INFORMATION

PrTHYMOGLOBULIN®
Anti-thymocyte Globulin [Rabbit]

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

ABOUT THIS MEDICATION

What the medication is used for:
Thymoglobulin® (Anti-thymocyte Globulin [Rabbit]) is used for treating acute kidney transplant rejection in conjunction with other medicines used to suppress the immune system. Thymoglobulin may also be used in the prevention of acute rejection in adult kidney transplant recipients.

What it does:
Thymoglobulin is an immune globulin and works by suppressing the body's immune system.

When it should not be used:
If you ever had an allergic reaction (for example rash, itchiness, or difficulty breathing) to rabbit products.
If you ever had an allergic reaction to any ingredient in Thymoglobulin.
If you have an active acute or chronic infection, which would contraindicate any additional immunosuppression.

What the medicinal ingredient is:
Anti-thymocyte Globulin [Rabbit]

What the important nonmedicinal ingredients are:
D-Mannitol, Glycine, Sodium Chloride

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

Thymoglobulin is supplied in a powder format that is mixed by a health care professional with Sterile Water for Injection prior to administration.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Thymoglobulin (Anti-thymocyte Globulin [Rabbit]) should only be used by physicians experienced in immunosuppressive therapy for the treatment of renal transplant patients. (see General section)
- In rare instances, serious immune-mediated reactions have been reported with the use of Thymoglobulin and consist of anaphylaxis or severe cytokine release syndrome (CRS). (see Immune section)

BEFORE you use Thymoglobulin talk to your doctor or pharmacist:

- If you plan to drive or operate machinery
- If you have an acute viral illness
- If you had severe or acute infections in the past
- If you are pregnant or plan to become pregnant or are breast feeding
- If you plan to be vaccinated or have recently been vaccinated
- If you are taking other medications

Medical surveillance is required during Thymoglobulin infusion.

INTERACTIONS WITH THIS MEDICATION

Live vaccines should not be administered when you are about to receive, receiving, or after treatment with Thymoglobulin.

The combination of Thymoglobulin, heparin, and hydrocortisone in a dextrose infusion solution has been noted to precipitate and is not recommended.

PROPER USE OF THIS MEDICATION

Usual dose:
The recommended dosage of Thymoglobulin (Anti-thymocyte Globulin [Rabbit]) for treatment of acute renal graft rejection is 1.5 mg/kg of body weight administered daily for 7 to 14 days. For prophylaxis in adult renal transplant recipients the recommended dose is 1.5 mg/kg/day intravenously for at least seven days beginning intraoperatively, through a high-flow vein.

Missed Dose:

If you missed a Thymoglobulin dose, contact your doctor.

Thymoglobulin will normally be administered by a health care professional in hospital.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Thymoglobulin can have side effects.

Symptom / effect	Talk with your doctor or pharmacist
Fever	✓
Shivering	✓
Shortness of breath, difficulty breathing, wheezing or coughing	✓
Feeling or being sick	✓
Dizzy or feeling faint	✓
Tiredness	✓
Muscle or joint pain	✓
Rash	✓
Headache	✓
Bleeding or bruising more easily	✓
Irregular or fast heartbeat	✓
Symptoms of infection such as fever, chills, sore throat, mouth ulcers	✓
Diarrhoea	✓

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

HOW TO STORE IT

You will not be asked to store your medicine.
Thymoglobulin will be stored in a refrigerator between+2°C and +8°C (36°F to 46°F). Protect from light. Do not freeze.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Canada Vigilance:

You can report any suspected adverse reactions associated with the use of health products in the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free telephone at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701C
    Ottawa, ON, K1A 0K9

Postage paid labels, Canada Vigilance Report Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of the side effect, please contact your health care professional. The Canada Vigilance program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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