PART III: CONSUMER INFORMATION

ATGAM* STERILE SOLUTION
(lymphocyte immunoglobulin, anti-thymocyte globulin [equine])

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

ABOUT THIS MEDICATION

What the medication is used for:
ATGAM (lymphocyte immunoglobulin, anti-thymocyte globulin [equine]) is indicated for any patient in whom reduction of peripheral T-lymphocyte function as measured by rosette-forming cell assay could be desirable. It is used at the time of kidney rejection as well as used with other therapies to delay the onset of a first rejection episode
It may also be used for other conditions in whom reduction of T-cell function could be desirable (ie: other allografts, bone marrow transplantation, aplastic anemia).

What it does:
ATGAM is an immunoglobulin 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) during prior administration of ATGAM or any other equine gamma globulin preparation.

What the medicinal ingredient is:
Each mL of ATGAM (lymphocyte immunoglobulin, anti-thymocyte globulin [equine]) contains 50 mg of horse gamma globulin stabilized in 0.3 molar glycine to a pH of approximately 6.8.

What the important nonmedicinal ingredients are:
Glycine

What dosage forms it comes in:
ATGAM is supplied in cartons of 5 X 5 mL ampoules containing 250 mg protein per ampoule.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Only physicians experienced in immunosuppressive therapy and management of renal transplant patients should use ATGAM.
- Treatment with ATGAM should be discontinued if any of the following occurs:
  1. Anaphylaxis
  2. Severe and unremitting thrombocytopenia
  3. Severe and unremitting leukopenia
- This product is manufactured using components of human blood which may contain the causative agent of hepatitis and other viral diseases. Prescribed manufacturing procedures utilized in blood collection centres and the plasma testing laboratories are designed to reduce the risk of transmitting viral infection. However, the risk of viral infectivity from this product cannot be totally excluded.
- When you are receiving ATGAM, you will be monitored in a facility equipped and staffed with adequate laboratory and supportive medical resources.

BEFORE you are administered ATGAM talk to your doctor or pharmacist if:

- 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 have any allergies to this drug or its ingredients or components of the container.
- If you are taking other medications.

No studies on the effect of ability to drive or use machines have been performed. Given the potential adverse reactions that may be experienced (e.g. dizziness, convulsion, confusion, fainting), caution should be taken when driving or using machinery while on this medication.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with ATGAM include:

- Live vaccines should not be administered when you are about to receive, receiving, or after treatment with ATGAM.
- Dilution of ATGAM in dextrose infusion solution is not recommended, as low salt concentration may result in precipitation. The use of highly acidic infusion solutions is also not recommended because of possible physical instability over time.
- When your dose of corticosteroids and other immunosuppressants is being reduced, some previously masked reactions to ATGAM may appear. Your

healthcare professional will monitor you when ATGAM is being infused.

PROPER USE OF THIS MEDICATION

Usual dose:
ATGAM will always be prepared and given to you by your doctor or healthcare professional.

It is possible that skin testing will be done by a healthcare professional prior to your first infusion of ATGAM.

The recommended dose of ATGAM for renal-allograft patients is 10 to 30 mg/kg of body weight daily. The recommended dose for delaying the onset of allograft rejection is 15 mg/kg daily for 14 days, then every other day for 14 days for a total of 21 doses in 28 days. The first dose should be administered within 24 hours before or after the transplant. The recommended dose for treatment of rejection is 10 to 15 mg/kg daily for 14 days. Additional alternate-day therapy up to a total of 21 doses can be given.

Other dosing regimens, depending on your condition, may be considered by your healthcare professional.

Missed Dose:
ATGAM will normally be administered by a health care professional in hospital. If you missed an ATGAM dose, contact your doctor

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.

Because of its mode of action and because it is a biologic substance, the maximum tolerated dose of ATGAM (lymphocyte immunoglobulin, anti-thymocyte globulin [equine]) would be expected to vary from one person to another. The incidence of toxicologic manifestations did not increase with any regimens.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects occurred at an incidence greater than 5%: chills, fever, leucopenia, thrombocytopenia, dermatological reactions (pruritis, rash, urticaria, wheal and flare).

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom/Effect	Talk With Your Doctor or Pharmacist
Chills	√
Fever	√
Leukopenia (decrease in white blood cells)	√
Thrombocytopenia (decrease in platelets)	√
Skin reactions (itching, rash, hives, wheal and flare)	√
Arthralgia (joint pain)	√
Chest and/or back pain	√
Clotting of the dialysis access	√
Diarrhea	√
Shortness of breath	√
Headache	√
Decreased blood pressure	√
Nausea and/or vomiting	√
Night sweats	√
Pain at the infusion site	√
Blood clot	√
Swelling of the mouth	√
Abnormal tests of liver function (SGOT, SGPT, alkaline phosphatase)	√
Abnormal tests of kidney function (serum creatinine)	√
Tachycardia (increased heart rate)	√
Bradycardia (decreased heart rate)	√

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

HOW TO STORE IT

Store ATGAM ampoules in the refrigerator at 2° to 8°C. Do not freeze. Protect the ampoules from light by storing in the carton.

REPORTING SUSPECTED SIDE EFFECTS

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

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, Ontario
    K1A 0K9

  Postage paid labels, Canada Vigilance Reporting 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 side effects, contact your health 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: http://www.pfizer.ca or by contacting the sponsor, Pfizer Canada Inc., at: 1-800-463-6001 (Medical Information)

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