PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

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

Read this carefully before you start taking **ATGAM** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ATGAM**.

Serious Warnings and Precautions

- Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should use ATGAM.
- Treatment with ATGAM should be discontinued if any of the following occurs:
    - Serious allergic reactions (anaphylaxis)
    - Severe and unremitting deficiency in blood platelets (thrombocytopenia)
    - Severe and unremitting low white blood cells (leukopenia)
- When you are receiving ATGAM, you will be monitored in a facility equipped and staffed with adequate laboratory and supportive medical resources.

What is ATGAM used for?

ATGAM (lymphocyte immunoglobulin, anti-thymocyte globulin [equine]) is indicated for any patient in whom reduction of T-lymphocyte function (white blood cells) could be desirable.

ATGAM is used at the time of organ transplant rejection (such as renal-allograft) as well as used with other therapies to delay the onset of a first rejection episode. It may also be used for the treatment of aplastic anemia.

How does ATGAM work?

ATGAM is an immunoglobulin (antibody) from horses that were immunized with human thymus lymphocytes. ATGAM works by suppressing the body's immune system (T-lymphocyte function).

What are the ingredients in ATGAM?

Medicinal ingredients: lymphocyte immunoglobulin, anti-thymocyte globulin [equine]

Non-medicinal ingredients: Glycine, Hydrochloric Acid, Sodium Hydroxide, Water for Injection

ATGAM comes in the following dosage forms:

Solution, 50 mg/mL (5 X 5 mL ampoules containing 250 mg protein per ampoule.)

Do not use ATGAM 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.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ATGAM. Talk about any health conditions or problems you may have, including if you:

- plan to drive or operate machinery
- have an acute viral illness
- had severe or acute infections in the past
- are pregnant or plan to become pregnant or are breast feeding
- plan to be vaccinated or have recently been vaccinated
- have any allergies to this drug or its ingredients or components of the container
- are taking other medications

Other warnings you should know about:

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.

This product is manufactured using components of human blood which may contain the causative agent of hepatitis and other viral diseases. 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.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ATGAM:

- Vaccination is not recommended in conjunction with ATGAM therapy as the effectiveness of the vaccines could be reduced.
- 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.

How to take ATGAM:

- ATGAM will be given to you by a healthcare professional in a healthcare setting.

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.

Overdose:

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.

If you think you, or a person you are caring for, have taken too much ATGAM, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using ATGAM?

These are not all the possible side effects you may have when taking ATGAM. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects with ATGAM are: chills, fever, leukopenia, thrombocytopenia, skin reactions (itching, rash, hives, wheal and flare).

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Chills		√	
Fever		√	
Leukopenia (decrease in white blood cells)		√	
Thrombocytopenia (decrease in platelets)		√	
Skin reactions (itching, rash, hives, wheal and flare)		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Arthralgia (joint pain)		√	
Chest and/or back pain		√	
Clotting of the dialysis access		√	
Diarrhea		√	
Allergic reactions (shortness of breath, swelling of the mouth)		√	
Headache		√	
Decreased blood pressure		√	
Nausea and/or vomiting		√	
Night sweats		√	
Pain at the infusion site		√	
Blood clot		√	
Abnormal tests of liver function (SGOT, SGPT, alkaline phosphatase)		√	
Abnormal tests of kidney function (serum creatinine)		√	
Tachycardia (increased heart rate)		√	
Bradycardia (decreased heart rate)		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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

Keep out of reach and sight of children.

If you want more information about ATGAM:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website http://www.pfizer.ca, or by calling 1-800-463-6001.

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