Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user
Lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution B.P.
ATGAM® Sterile Solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Atgam is and what it is used for

Atgam is made by injecting human thymus cells into horses. It contains immunoglobulins (antibodies) which attach to and destroy some of the cells of the immune system in your body. It is used for the following indications:

Renal Allograft Rejection

Atgam is indicated for the management of allograft rejection in renal transplant patients; when administered with conventional therapy at the time of rejection Atgam increases the frequency of resolution of the acute rejection episode.

Aplastic Anemia

Atgam is indicated for the treatment of moderate to severe aplastic anemia in patients unsuitable for bone marrow transplantation.

The usefulness of Atgam has not been demonstrated in patients with aplastic anemia who are suitable candidates for bone marrow transplantation or in patients with aplastic anemia secondary to neoplastic disease, storage disease, myelofibrosis, Fanconi's syndrome, or in patients known to have been exposed to myelotoxic agents or radiation.

2. What you need to know before you take Atgam

Do not receive Atgam

- If you had an allergic reaction during prior administration of Atgam or any other equine gamma globulin preparation

Warnings and precautions

Tell your doctor immediately if you experience any of these serious and potentially life-threatening side effects of Atgam (these symptoms that require immediate contact with your doctor are repeated again in section 4):

- Any serious infections: symptoms may include fever, sweating, chills, muscle aches, cough, shortness of breath, warm or red or painful skin or sores on your body, diarrhoea or stomach pain;
- Allergic reactions: symptoms may include generalised rash, increased heart rate, difficulty breathing, decreased blood pressure and weakness;
- Serum sickness: it is a delayed hypersensitivity/immune reaction. an allergic reaction that causes fever, aches and pains in the joints, skin rash, chills, and swollen lymph glands have been reported. Tell your doctor immediately if you experience any signs of serum sickness.
- Cytokine release syndrome: It has been reported with the use of Atgam. It can be fatal. Clinical signs may include fever, chills, headache, chest pain, hypotension, dyspnea, tachypnea, and edema. Tell your doctor immediately if you experience any signs of Cytokine release syndrome.
- Infusion-Associated Reactions: Serious infusion-associated reactions have been reported with the use of ATGAM. Clinical signs associated with infusion-associated reactions include generalized rash, increased heart rate, difficulty in breathing, and low blood pressure. Tell your doctor immediately if you experience any signs of infusion-associated reactions.

Transmissible Infectious Agents

Because ATGAM is made from equine and human blood components, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. This also applies to unknown or emerging viruses and other pathogens. Tell your doctor immediately if you experience any symptoms of an infection.

Immunizations

Tell your doctor before taking any live vaccines, when you are receiving, about to receive or after the treatment with Atgam as it may result in uncontrolled viral replication in immunocompromised patients. If administered, live viruses may interfere with Atgam treatment.

Additional tests

To identify if you have a greater risk of severe allergic reactions, skin testing might be performed before treatment. Testing will check for allergy to any of the ingredients of Atgam. Results of the test will help the doctor to decide whether or not Atgam can be given.

Hepatic and Renal Function Tests

Abnormal liver and kidney function testresult can occur when patients with aplastic anaemia are treated with Atgam.

Other medicines and Atgam

Tell the doctor if you are taking, have recently taken, or might take any other medicines.

When the dose of corticosteroids and other immunosuppressants is being reduced, some previously hidden reactions to Atgam may appear. You will be carefully observed during the infusion of Atgam to check for this.

Pregnancy and breast-feeding

Pregnancy

Tell your doctor if you think you may be pregnant.

It is not known whether Atgam affects an unborn child during pregnancy.

Atgam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Breast-feeding

Tell your doctor if you are breast-feeding or planning to breast-feed.

It is not known whether Atgam passes into breast milk. A risk to the breast-fed child cannot be excluded.

You and your doctor should decide if you should breast-feed or be treated with Atgam.

Females and Males of Reproductive Potential

Females

It is not known if Atgam can cause fetal harm when administered to a pregnant woman. if planning to have a child. Females are advised to use effective contraception during treatment with Atgam and for at least 10 weeks after discontinuation of therapy

Males

Advise males with a female partner of reproductive potential to use effective contraception during treatment with Atgam and for at least 10 weeks after discontinuation of therapy

Driving and using machines

Atgam may influence your ability to drive and use machines. Caution should be taken when driving or using machinery while on this medication.

3. How Atgam is given

Atgam will be infused into a vein by the doctor or a health care professional. You should check with your doctor for additional information.

Dosing recommendations are based on body weight.

Renal Allograft Recipients

Renal transplant rejection: The recommended dose is 10 to 15 mg/kg daily intravenously for 14 days. Additional alternate-day therapy up to a total of 21 doses may be given.

Aplastic Anemia (Moderate to Severe)

The recommended dose is 10 to 20 mg/kg daily intravenously for 8 to 14 days. Additional alternate-day therapy up to a total of 21 doses may be given.

If you receive more Atgam than you should

Since Atgam will be given by a doctor, it is very unlikely that more than the recommended dose of Atgam will be given. If you think that a larger dose of Atgam than prescribed has been given to you, tell the doctor immediately.

If you have further questions on the use of this medicine, ask your doctor.

If you forget to use Atgam

Since Atgam will be given to you by your doctor it is very unlikely that you would not receive the medicine at the proper time. If you think you have not been given Atgam at the appropriate time, tell your doctor immediately.

If you have further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of these serious and potentially life-threatening side effects of Atgam (these symptoms that require immediate contact with the doctor are mentioned also in section 2 above):

- Serious infections: symptoms may include fever, sweating, chills, muscle aches, cough, shortness of breath, warm or red or painful skin or sores on your body, diarrhoea or stomach pain;
- Allergic reactions: symptoms may include generalised rash, increased heart rate, difficulty breathing, decreased blood pressure and weakness;
- Serum sickness: an allergic reaction that causes fever, aches and pains in the joints, skin rash and swollen lymph glands;

Other side effects

Side effects occurring in ≥1% of Patients who Received ATGAM:

- Fever, chills, headache
- Low platelet and white cell count (Thrombocytopenia)
- Skin rashes, skin redness, skin itching, skin irriration
- Pain, including joints, back and chest
- Infusion site pain
- Infection
- High or low blood pressure
- Diarrhoea, abdominal pain, nausea, vomiting
- Swelling and pain in the part of the body caused by a local blood clot in the vein
- Swelling due to excess fluid buildup (Edema)
- Enlarged or swollen lymph nodes (Lymphadenopathy)
- An inflammatory process that causes a blood clot to form and block one or more veins, usually in the legs (Thrombophlebitis)
- Dizziness
- Breathlessness, difficulty breathing
- Rapid or slow heart rate
- Abnormal liver function tests

Side effects occurring in <1% of Patients who Received ATGAM:

- Seizure
- Fluid in the lungs (Pulmonary edema and build-up of excess fluid between the layers of the pleura outside the lungs (Pleural effusion)
- Night sweats
- Allergic reaction to proteins in the antiserum (Serum sickness)
- Increased blood sugar
- Sores in the mouth, swelling of the mouth, mouth pain
- Abnormal kidney function tests
- Herpes simplex
- Agitation
- Hiccups
- High levels of protein in urine (Proteinuria)
- Feeling unwell and lack of energy or strength
- Wound splitting
- Serious allergic reaction including hives, shortness of breath or difficulty breathing, temporary stopping of breathing (Anaphylactic reaction)
- Inflammation of the brain (Encephalitis)
- Tingling or numbness in hands or legs
- Kidney abnormalities
- Inflammation of skin due to allergy
- Swelling around the eyes
- Life-threatening skin disorder characterized by a blistering and peeling of the skin (Toxic epidermal necrolysis)

Side effects whose frequency cannot be estimated from the available data (Post-Marketing Experience)

- Infection (Localized or Systemic), bacterial, viral, fungal
- Serious infection of the blood
- Reduced blood cells
- Confusion, tremors, fainting
- Blood clot in the leg which causes pain, swelling or redness and Inflammation of vessels
- Cough, nose bleed, oral pain
- Clot in the blood vessels of the intestine, hole in the intestine (perforation), abdominal pain
- Increased sweating
- Difficulty moving, muscle pain and stiffness
- Heart and Kidney failure
- Lack of development of cells
- Infusion site redness, swelling, pain

5. How to store Atgam

Store at 2°C to 8°C. Do not freeze.

Store in the original carton to protect from light. Diluted solution can be kept at room temperature. The solution should be used within 24 hours (including infusion time).

6. Contents of the pack and other information

What Atgam contains

- Atgam contains lymphocyte immune globulin, anti-thymocyte globulin [equine]. It is the purified, concentrated, and sterile gamma globulin, primarily monomeric IgG, from hyperimmune serum of horses immunized with human thymus lymphocytes. Each milliliter of Atgam contains 50 mg of horse gamma globulin stabilized in 0.3 molar glycine to a pH of approximately 6.8.
- The other ingredient(s) are glycine, Water for Injections, sodium hydroxide (for pH adjustment), and hydrochloric acid (for pH adjustment) (see section 2 “Atgam contains sodium”).

What Atgam looks like and contents of the pack

Atgam is a transparent to slightly opalescent, colourless to light pink or brown sterile aqueous solution and is nearly odourless. It may develop a slight granular or flaky deposit during storage.

It is supplied in a set of 5 ampoules. Each ampoule contains 5 mL of Atgam Sterile Solution, having 50 mg of lyophilized ATG (Equine) per ml.

Imported and Marketed by:

Pfizer Products India Private Limited,
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Manufactured by:

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