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Atgam (Lymphocyte immune globulin)

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Renal Transplantation

The primary clinical experience with ATGAM (lymphocyte immune globulin) Sterile Solution has been in renal allograft patients who were also receiving concurrent standard immunosuppressive therapy (azathioprine, corticosteroids). In controlled trials, investigators frequently reported the following adverse reactions: fever in 1 patient in 3; chills in 1 patient in 7; leukopenia in 1 patient in 7; thrombocytopenia in 1 patient in 9; and dermatologic reactions, such as rash, pruritus, urticaria, wheal, and flare, in 1 patient in 8. The following reactions were reported in more than 1% but less than 5% of the patients: arthralgia; chest or back pain, or both; clotted A/V fistula; diarrhea; dyspnea; headache; hypotension; nausea or vomiting, or both; night sweats; pain at the infusion site; peripheral thrombophlebitis; and stomatitis.

Reactions reported in less than 1% of the patients in the controlled trials were anaphylaxis, dizziness, weakness or faintness, edema, herpes simplex reactivation, hiccoughs or epigastric pain, hyperglycemia, hypertension, iliac vein obstruction, laryngospasm, localized infection, lymphadenopathy, malaise, myalgia, paresthesia, possible serum sickness, pulmonary edema, renal artery thrombosis, seizures, systemic infection, tachycardia, toxic epidermal necrosis, and wound dehiscence.

Aplastic Anemia

In premarketing clinical trials with ATGAM (lymphocyte immune globulin) in the treatment of aplastic anemia, patients were also being concurrently managed with support therapy (transfusions, steroids, antibiotics, antihistamines).

In these trials most patients experienced fever and skin reactions. Other frequently reported adverse reactions were chills, 1 patient in 2; arthralgia, 1 patient in 2; headache, 1 patient in 6; myalgia, 1 patient in 10; nausea, 1 patient in 15; chest pain, 1 patient in 15 and phlebitis, 1 patient in 20.

The following reactions were reported by at least one patient and less than 5% of the total patients: diaphoresis, joint stiffness, periorbital edema, aches, edema, muscle ache, vomiting, agitation/lethargy, listlessness, light-headedness, seizures, diarrhea, bradycardia, myocarditis, cardiac irregularity, hepatosplenomegaly, -possible encephalitis or post viral encephalopathy, hypotension, congestive heart failure, hypertension, burning soles/palms, foot sole pain, lymphadenopathy, post cervical lymphadenopathy, tender lymph nodes, bilateral pleural effusion, respiratory distress, anaphylactic reaction, and proteinuria.

In other support studies in patients with aplastic anemia and other hematologic abnormalities who have received ATGAM (lymphocyte immune globulin) , abnormal tests of liver function (SGOT, SGPT, alkaline phosphatase) and renal function (serum creatinine) have been observed. In some trials, clinical and laboratory findings of serum sickness were seen in a majority of patients.

Postmarketing Experience

During approximately 5 years of post approval marketing experience, the frequency of adverse reactions in voluntarily reported cases is as follows: fever 51%; chills 16%; thrombocytopenia 30%; leukopenia 14%; rashes 27%; systemic infection 13%. Events reported in 5% to 10% of reported cases include abnormal renal function tests; serum sickness-like symptoms; dyspnea/apnea; arthralgia; chest, back, or flank pain; diarrhea and nausea and/or vomiting. Events reported with a frequency of less than 5% include: hypertension, Herpes Simplex infection, pain, swelling or redness at infusion site, eosinophilia, headache, myalgias, or leg pains, hypotension, anaphylaxis, tachycardia, edema, localized infection, malaise, seizures, GI bleeding or perforation, deep vein thrombosis, sore mouth/throat, hyperglycemia, acute renal failure, abnormal liver function tests, confusion or disorientation, cough, neutropenia or granulocytopenia, anemia, thrombophlebitis, dizziness, epigastric or stomach pain, lymphadenopathy, pulmonary edema or congestive heart failure, abdominal pain, nosebleed, vasculitis, aplasia or pancytopenia, abnormal involuntary movement or tremor, rigidity, sweating, laryngospasm/edema, hemolysis or hemolytic anemia, viral hepatitis, faintness, enlarged or ruptured kidney, paresthesias, and renal artery thrombosis.

The recommended management for some of the adverse reactions that could occur with treatment with ATGAM (lymphocyte immune globulin) follows:

1. **Anaphylaxis** is uncommon but serious and may occur at any time during therapy with ATGAM (lymphocyte immune globulin) . Stop infusion of ATGAM (lymphocyte immune globulin) immediately; administer 0.3 mL aqueous epinephrine (1:1,000 solution) intramuscularly. Administer steroids; assist respiration; and provide other resuscitative measures. DO NOT resume therapy with ATGAM (lymphocyte immune globulin) .
2. **Hemolysis** can usually be detected only in the laboratory. Clinically significant hemolysis has been reported rarely. Appropriate treatment of hemolysis may include transfusion of erythrocytes; if necessary, administer intravenous mannitol, furosemide, sodium bicarbonate, and fluids. Severe and unremitting hemolysis may require discontinuation of therapy with ATGAM (lymphocyte immune globulin) .
3. **Thrombocytopenia** is usually transient in renal transplant patients; platelet counts generally return to adequate levels without discontinuing therapy with ATGAM (lymphocyte immune globulin) . Platelet transfusions may be necessary in patients with aplastic anemia. (See **PRECAUTIONS,**

)**DOSAGE AND ADMINISTRATION.** and**WARNINGS,**

4. **Respiratory distress** may indicate an anaphylactoid reaction. Discontinue infusion of ATGAM (lymphocyte immune globulin) . If distress persists, administer an antihistamine, epinephrine, corticosteroids, or some combination of the three.
5. **Pain in chest, flank, or back** may indicate anaphylaxis or hemolysis. Treatment is that indicated above for those conditions.
6. **Hypotension** may indicate anaphylaxis. Stop infusion of ATGAM (lymphocyte immune globulin) and stabilize blood pressure with pressors if necessary.
7. **Chills and fever** occur frequently in patients receiving ATGAM (lymphocyte immune globulin) . ATGAM (lymphocyte immune globulin) may release endogenous leukocyte pyrogens. Prophylactic and/or therapeutic administration of antihistamines, antipyretics, or corticosteroids generally controls this reaction.
8. **Chemical phlebitis** can be caused by infusion of ATGAM (lymphocyte immune globulin) through peripheral veins. This can often be avoided by administering the infusion solution into a high-flow vein. A subcutaneous arterialized vein produced by a Brescia fistula is also a useful administration site.
9. **Itching and erythema** probably result from the effect of ATGAM (lymphocyte immune globulin) on blood elements. Antihistamines generally control the symptoms.
10. **Serum sickness-like symptoms** in aplastic anemia patients have been treated with oral or IV corticosteroids. Resolution of symptoms has generally been prompt and long-term sequelae have not been observed. Prophylactic administration of corticosteroids may decrease the frequency of this reaction.