Abbreviated Prescribing Information

Thymoglobuline 5mg/ml powder for solution for infusion.
Qualitative And Quantitive composition: After reconstitution: Rabbit anti-human thymocyte immunoglobulin 5 mg/mL Equivalent to 25 mg/5 mL of rabbit anti-human thymocyte immunoglobulin per vial. **Indications**: -Immunosuppression in transplantation: prevention and treatment of graft rejection. -Prevention of acute or chronic graft-versus-host disease in hematopoietic stem cell Transplantation -Treatment of steroid-resistant acute graft-versus-host disease-Hematology: Treatment of aplastic anemia. **Posology: -**Immunosuppression in transplantation: Prophylaxis of acute graft rejection: 1 to 1.5 mg/kg/day for 2 to 9 days after kidney, pancreas or liver transplant, and for 2 to 5 days after heart transplant. A cumulative dose of 2 to 7.5 mg/kg for heart transplant and 2 to 13.5 mg/kg for other organs.- Treatment of acute graft rejection: 1.5 mg/kg/day for 3 to 14 days, i.e., a cumulative dose of 4.5 to 21 mg/kg.- Prevention of acute and chronic graft-versus-host disease. In the case of transplants (bone marrow or peripheral blood hematopoietic stem cells) from related non-HLA-identical or unrelated HLA-identical donors, it is recommended that, in adult patients, Thymoglobuline be administered as preliminary treatment at a dose of 2.5 mg/kg/day from day -4 today -2 or -1. A cumulative dose of 7.5 to 10 mg/kg. -Treatment of steroid-resistant acute graft-versus-host disease. Dosage should be determined on a case-by-case basis. It is usually between 2 and 5 mg/kg/day for 5 days. -Treatment of aplastic anemia: 2.5 to 3.5 mg/kg/day for 5 consecutive days, i.e., a cumulative dose of 12.5 to 17.5 mg/kg. **Method of administration:** Thymoglobuline is usually administered in the context of a therapeutic protocol combining several immunosuppressants. Premedication with intravenous corticosteroids and antihistamines should be administered prior to infusion of rabbit anti-human thymocyte immunoglobulin. Infuse slowly into a high-flow vein. Adjust the infusion rate so that the total duration of infusion is not less than 4 hours. **Contraindications:** Thymoglobuline is contraindicated in patients with: Hypersensitivity to rabbit proteins or to any product excipients, Acute or chronic infections. **Special warnings and precautions for use:** Thymoglobulin should always be administered under strict medical monitoring in a hospital environment. Patients should be closely monitored during the infusion and for a certain length of time after the end of the infusion and until they are stable. **Warnings:** -Liver disease: Platelets and coagulation factors should be particularly carefully monitored. -Immune-mediated reactions: Rare cases of serious immune-mediated reactions have been reported with the use of Thymoglobuline, consisting of anaphylaxis or severe cytokine release syndrome (CRS). –Infections: Thymoglobuline is routinely used in combination with other immunosuppressants. Infections (bacterial, fungal, viral and protozoal), reactivation of infection (particularly cytalomegalovirus [CMV]) and sepsis have been reported after administration of Thymoglobuline in combination with multiple immunosuppressants. In rare cases, these infections have been fatal. Physicians should therefore exercise care to ensure that the dose prescribed is appropriate for the ATG product being administered. Premedication with antipyretics, corticosteroids, and/or antihistamines may decrease both the incidence and severity of these adverse reactions. Rapid infusion rates have been associated with cytokine release syndrome (CRS). In rare instances, severe CRS can be fatal. **Precautions to use**: -General population: Appropriate dosing for Thymoglobuline is different from dosing for other anti-thymocyte globulin (ATG) products, as protein composition and concentrations vary depending on the source of ATG used. Physicians must therefore ensure that the dose prescribed is appropriate for the ATG product being administered. -Hematological effects: Thrombocytopenia and/or leukopenia (including lymphocytopenia and neutropenia) have been observed and are reversible following dose adjustments. When thrombocytopenia and/or leukopenia are not associated with the underlying disease or the condition for which Thymoglobuline is being administered, dose reductions are suggested.-Infection: Infections, reactivation of infection and sepsis have been reported following administration of Thymoglobuline in combination with multiple immunosuppressants. Careful patient monitoring and appropriate anti-infective prophylaxis are recommended.-Malignancy: Use of immunosuppressants, including Thymoglobuline, may increase the incidence of malignancies, particularly lymphoma or lymphoproliferative disorders.-Risk of transmission of infectious agents: Products of human origin are used in the manufacturing process for rabbit immunoglobulin. Standard measures to prevent infections resulting from the use of medicinal products prepared using human components involve careful selection of starting materials and implementation of effective steps for inactivation/removal of viruses in the manufacturing process.- Special consideration: As with any infusion, reactions at the injection site can occur and may include pain, swelling and erythema. – Immunization: The safety of immunization with live attenuated vaccines following Thymoglobuline therapy has not been studied; therefore, immunization with live attenuated vaccines is not recommended for patients who have recently received Thymoglobuline. **Interaction with other medicinal products and other forms of interaction: -** Combinations to be taken into account: *Ciclosporin, tacrolimus, mycophenolate mofetil. Risk of excessive immunosuppression with risk of lymphoproliferation.*Live attenuated vaccines: Risk of potentially fatal systemic infection due to the vaccine. Immune mediated reaction. Infection, reactivation of infection, and sepsis have been often reported with thymoglobuline administration in combination with multiple immunosuppressive agents. **Fertility, pregnancy and lactation:** No reproductive toxicity studies have been conducted with Thymoglobuline. The potential risk for humans is unknown. Thymoglobuline should not be administered during pregnancy unless absolutely necessary. It is not known whether rabbit anti-human thymocyte immunoglobulin is excreted in human milk. Because other immunoglobulins are excreted in human milk, breast-feeding should be discontinued during Thymoglobuline therapy. **Undesirable effects:** Blood and lymphatic system disorders: lymphopenia, neutropenia, thrombocytopenia .Gastrointestinal disorders: Diarrhoea, dysphagia, nausea, vomiting .General disorders and administrative site conditions :Fever ,Shivering .Immune system disorders: Serum sickness ,Infections and infestations: Infection .Musculoskeletal and connective tissue disorders: Myalgia. ,Neoplasms benign, malignant and unspecified (including cysts and polyps):Malignancy .Respiratory, thoracic mediastinal disorders :Dyspnea .Skin and subcutaneous tissue disorder: Pruritus, rash .Vascular disorder: Hypotension .Adverse events due to immunosuppression :Infections, reactivation of infection, febrile neutropenia, and sepsis **Overdose:** Accidental overdose may induce leukopenia (including lymphocytopenia and neutropenia) and thrombocytopenia. These effects are reversible after dose adjustments or treatment discontinuation. There is no antidote. **Special precautions for storage:** Store in a refrigerator (2°C - 8°C). Do not freeze. Revision date: September 2023.

If you have any Medical enquiry, please email us at levant.medinfo@sanofi.com To report an adverse event or any pharmacovigilance case, please email us at Levant.Pharmacovigilance@sanofi.com

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