For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Antihuman thymocyte immunoglobulin (Rabbit) E.P.

THYMOGLOBULINE® 5mg/ml
Powder for concentrate for a solution for infusion

COMPOSITION
After reconstitution with 5ml Water for Injection (WFI) I.P., the solution contains 5mg rabbit anti-human thymocyte immunoglobulin/ ml (concentrate) Corresponding to 25mg/5ml of rabbit anti-human thymocyte immunoglobulin per vial.

THERAPEUTIC INDICATIONS
- Immunosuppression in transplantation: prophylaxis and treatment of graft rejection.
- Prophylaxis of acute and chronic graft versus host disease in haematopoietic stem cell transplantation.
- Treatment of steroid-resistant, acute graft versus host disease.
- Haematology: treatment of aplastic anaemia.

DOSAGE AND ADMINISTRATION
The posology depends on the indication, the administration regimen and the possible combination with other immunosuppressive agents. Recommendations may be used as reference. The treatment may be discontinued without gradual reduction of dose. Administer doses of corticosteroids and antihistamines are required prior to infusion of rabbit anti-human thymocyte immunoglobulin.

SAFETY-RELATED INFORMATION
Contraindications: Acute or chronic infections, which would contraindicate any additional immunosuppression. Hypersensitivity to rabbit proteins or to any product excipients.

Pregnancy and Lactation: Thymoglobuline® should not be given unless absolutely required. Breast feeding should be discontinued.

Warnings and Precautions: Must be used in a hospital setting. Acute Infusion –associated reaction (IARs) may occur following the administration of Thymoglobuline and may occur as soon as the first or second infusion during a single course of Thymoglobuline treatment. In the event of an anaphylactic shock, the infusion has to be stopped immediately, and any further administration must only be carried out after the benefits and the risks have been carefully weighed up. Thrombocytopenia and/or leucopenia have been identified: white blood cell and platelet count must be monitored during and after the treatment. Infections, reactivation of infection, and sepsis have been reported after administration of Thymoglobuline in association with several immunosuppressive agents. The use of immunosuppressive agents, including Thymoglobuline may increase the incidence of malignancies. Reactions at the infusion site can occur and may include pain, swelling, and erythema. Immunization with attenuated live vaccines is not recommended for patients who have recently received Thymoglobuline.

ADVERSE REACTIONS: Infection (including reactivation of infection), Sepsis, Lymphoproliferative disorder, Lymphomas (which may be virally mediated), Neoplasms malignant (Solid tumors), Febrile neutropenia, Disseminated intravascular coagulopathy, Coagulopathy, Cytokine release syndrome (CRS), Anaphylactic reaction , Serum Sickness (including reactions such as fever, rash, urticaria, arthralgia, and/or myalgia), Transaminases increased, Hepatocellular injury, Hepatotoxicity, Hepatic Failure, Infusion related reactions (Infusion associated Reactions (IARs)

For full prescribing information please contact: Sanofi Healthcare India Private Limited, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

Updated: July 2025
Source: 1)) CCDS version no. 2 dated 16 July 2015.
2) UK Summary of Product characteristics dated 13th November 2020.