PACKAGE INSERT – Thymoglobuline – Powder for solution for infusion

NAME OF THE MEDICINE

Anti-thymocyte globulin [rabbit], rATG.

DOSAGE FORM

Powder for solution for infusion

METHOD OF PREPARATION

Preparation:

Use Aseptic Technique

A volume of 5mL water for injection is required to reconstitute the finalised product in the 10mL vial to give a nominal rabbit anti-human thymocyte immunoglobulin concentration of 5mg/mL. The reconstituted Thymoglobuline solution is further diluted with 0.9% sodium chloride injection (USP/EP) or 5% glucose solution prior to intravenous administration.

1. Determine the number of vials to be reconstituted based on the individual patient's weight and the recommended dose.

   Remove the required number of vials from the refrigerator and allow them to reach room temperature prior to reconstitution (approximately 30 minutes).

2. Reconstitute each vial by slowly injecting 5mL of sterile water for injection to the inside wall of each vial. Each reconstituted vial will yield 5mg/mL or 25mg of Thymoglobuline. Avoid forceful impact of the water for injection on the powder and avoid foaming. This is done by slow drop-wise addition of the water for injection down the inside of the vial and not directly onto the lyophilised cake. Tilt and roll each vial gently. Do not invert, swirl, or shake.

3. Perform an immediate visual inspection on the reconstituted vials for particulate matter and discolouration. The solution is clear or slightly opalescent. Inspect solution for particulate matter after reconstitution. Should some particulate matter remain, continue to gently rotate the vial until no particulate matter remains. If upon inspection particulate matter remains or if the solution is discoloured do not use.

4. Withdraw the calculated volume of Thymoglobuline from the appropriate number of vials and transfer the contents of the calculated number of Thymoglobuline vials into the bag of infusion solution (0.9% sodium chloride or 5% glucose solution). Recommended volume: per 1 vial of Thymoglobuline use 50mL of infusion solution (total volume usually between 50 to 500mL).

5. Gently invert or massage the infusion bag to mix. Do not shake. To reduce microbial hazard, use as soon as practicable after dilution. If storage is necessary, hold at 2°C-8°C for no more than 24 hours. Protect from light.

6. Set the flow rate to deliver the dose over a minimum of 6 hours for the first dose and over at least 4 hours for subsequent doses.

To minimise inadvertent administration of particulate matter from reconstitution it is recommended that Thymoglobuline is administrated through a 0.22 µm in-line filter. Thymoglobuline should not be infused in the same intravenous line with other products.

Compatibility:

It is recommended to administer pre-medication with intravenous corticosteroids and antihistamines prior to infusion of rabbit anti-human thymocyte immunoglobulin. Anti-pyretic agents (e.g. paracetamol) may also increase the tolerability of the initial infusion.

Based on a single compatibility study, the combination of Thymoglobuline, heparin and hydrocortisone in a dextrose infusion solution has been noted to precipitate and is not recommended. In the absence of additional pharmaceutical incompatibility data, Thymoglobuline should not be mixed with other medicinal products in the same infusion.

IN-USE STORAGE CONDITIONS

This product contains no preservatives. The diluted solution should be used immediately in order to prevent microbial contamination. If not used immediately, the diluted solution should be stored refrigerated at 2°C–8°C. Storage after dilution should not exceed 24 hours from the time of preparation to the completion of administration unless reconstitution or dilution has taken place in controlled and validated aseptic conditions. Protect from light.

SPONSOR

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