

PACKAGE INSERT – Lemtrada – Injection concentrated vial

NAME OF THE MEDICINE

Alemtuzumab (rch)

DOSAGE FORM

Injection, concentrated.

METHOD OF PREPARATION

Preparation:

Lemtrada vials should be inspected for particulate matter and discoloration prior to administration. Do not use if particulate matter is present or the solution is discoloured.

For IV administration, withdraw 1.2 mL of Lemtrada from the vial and inject into 100 mL sterile 0.9% sodium chloride or 5% dextrose/glucose in water. Gently invert the bag to mix the solution.

Lemtrada contains no antimicrobial preservatives and therefore care should be taken to ensure the sterility of the prepared solution. Product is for single use in one patient only.

To reduce microbiological hazard, use as soon as practical after preparation.

Compatibility:

Alemtuzumab should not be mixed with other medicinal products. Do not add or simultaneously infuse other medicinal products through the same intravenous line.

There are no known incompatibilities between Lemtrada and PVC infusion bags, or PVC or polyethylene-lined PVC administration sets or low protein binding filters.

IN-USE STORAGE CONDITIONS

Lemtrada diluted product may be stored for not more than 6 hours at room temperature (15°C to 25°C) or for not more than 8 hours at refrigerated conditions (2°C to 8°C). Do not freeze or shake. Protect from light. Partially used, unused, or damaged drug vials should be disposed of in accordance with local requirements.

SPONSOR

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