

PACKAGE INSERT – MabCampath – Concentrate solution for infusion vial

NAME OF THE MEDICINE

Alemtuzumab (rch)

DOSAGE FORM

Injection, concentrated

METHOD OF PREPARATION

Preparation:

The vial contents should be inspected for particulate matter and discolouration prior to administration. If particulate matter is present or the concentrate is coloured, then the vial must not be used.

MabCampath contains no antimicrobial preservatives, therefore, it is recommended that it should be prepared using aseptic techniques and that the diluted solution for infusion should be administered within 8 hours after preparation. The required amount of the vial contents should be added to 100 mL of 0.9% sodium chloride solution or 5% glucose solution. The bag should be inverted gently to mix the solution.

Women who are pregnant or planning pregnancy should not handle MabCampath.

Caution should be exercised in the handling and preparation of the MabCampath solution. The use of latex gloves and safety glasses is recommended to avoid exposure in case of breakage of the vial or other accidental spillage.

Procedures for proper handling and disposal should be observed. Any spillage or waste material should be disposed of by incineration.

Compatibility:

This medicinal product should not be reconstituted with solvents other than those mentioned above.

There are no known incompatibilities with other medicinal products. However, other medicinal products should not be added to the MabCampath infusion solution or simultaneously infused through the same intravenous line.

IN-USE STORAGE CONDITIONS

MabCampath contains no antimicrobial preservative. To reduce microbiological hazard, use as soon as practicable after reconstitution / preparation. If storage is necessary, hold at 2°C to 8°C for not more than 8 hours. This can only be accepted if preparation of the solution takes place under strictly aseptic conditions and the solution is protected from light.

SPONSOR

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