MabThera® SC 1,400 mg

SOLUTION FOR SUBCUTANEOUS INJECTION

Rituximab FOR NHL ONLY*

GUIDE

to supply, storage, handling and administration

Produced by Roche for Healthcare professionals who are administering MabThera SC to their patients with Non Hodgkin's Lymphoma (NHL)

EXCLUSIVE MATERIAL FOR HEALTHCARE PROFESSIONALS

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Affiliate Patient Safety Unit Version 2.0 2022

This leaflet is a guide for physicians, nurses and pharmacists to the safe and efficient use of MabThera 1,400 mg solution for subcutaneous injection (referred to as MabThera SC). The enclosed information pertains to the supply, storage, handling and administration of MabThera SC. The guidance given is specific to the subcutaneous formulation only.

Supply, storage and handling of MabThera 1,400 mg solution for subcutaneous injection†

How MabThera SC is supplied?

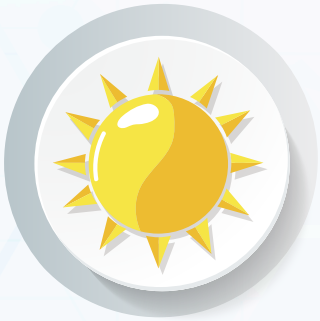
- Each carton contains one glass vial.
- Each vial contains 11.7 mL of sterile, non-pyrogenic and preservative - free solution (extractable volume is equivalent to one dose for administration to the patient).
- The solution is clear to opalescent, colourless to yellowish.
  Do not use if you notice unusual coloration or presence of visible particles.

Composition?

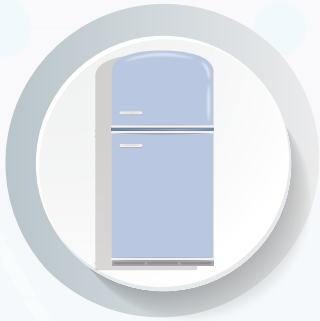
- The active ingredient of MabThera SC is rituximab (1,400 mg per vial).
- The excipients are:
  - Recombinant human hyaluronidase (rHuPH20): this is an enzyme used to increase the dispersion and absorption of co-administered drugs when administered subcutaneosly.
    It allows the injection of large volumes via the subcutaneous route.
  - Other excipients: L-histidine, L-histidine hydrochloride monohydrate, α,α-trehalose dihydrare, L-methionine, polysorbate 80 and water for injections.
- The pH of the solution is between 5 and 6

† Please refer to the Summary of Product Characteristics for further information or contact your local Roche representative.

How MabThera SC should be stored?



Keep the vial in the outer carton to protect MabThera SC from the light.



Store MabThera in refrigerator (2 - 8ºC). **DO NOT FREEZE**

Check the expiration date on the outer carton.

How to handle MabThera SC

- Before handling MabThera SC, please check the packaging to ensure you have the correct formulation. This is in order to avoid any confusion with MabThera concentrate for solution for infusion, which has a different packaging color code.

Check for the specific MabThera SC packaging characteristics:

1. Red labelling: ‘For subcutaneous use only’, ‘solution for subcutaneous injection’ and ‘SC’
2. Pink flip-off cap

- MabThera SC is ready to use; the whole content of the vial (1,400 mg rituximab) should be injected.
- MabThera SC does not contain any antimicrobial preservative and, as with all unpreserved sterile solutions, should be used immediately.
- No incompatibilities have been observed between MabThera SC and the following: polypropylene or polycarbonate syringe material, stainless steel transfer and injection needles, polyethylene Luer cone stoppers.

Administration of MabThera 1,400 mg solution for subcutaneous injection†

Important reminder

- **All patients must receive their first dose of MabThera by intravenous infusion, using MabThera concentrate for solution for infusion. MabThera SC should only be given at the second or subsequent cycle of treatment.**

- Premedication consisting of an anti-pyretic and an anti-histaminic, e.g. paracetamol and diphenhydramine, should always be given before each administration of MabThera.
  Premedication with glucocorticoids should be considered if MabThera is not given in combination with glucocorticoid-cointaining chemotherapy for the treatment of NHL.

- MabThera SC should be administered in an environment where full resuscitation facilities are immediately available and under the close supervision of an experienced healthcare professional.

Prepare the patient for injection

The patient should be asked to lean back in a reclining chair or a bed and to make their abdominal region accessible for injection.

† Please refer to the Summary of Product Characteristics for further information or contact your local Roche representative.

2 Prepare the injection site

- The selected abdominal site should be thoroughly disinfected as per local practice.
- Each injection should be given at a different site and never into areas where the skin is red, bruised, tender, hard, or into areas where there are moles or scars.

3 Prepare MabThera SC for injection

- The syringe should be prepared at the time of its administration.
- Ensure use of a needle suitable for subcutaneous injection.
- Attach the hypodermic injection needle to the syringe immediately prior to administration to avoid potential needle clogging.
- The whole content of the vial (1,400 mg rituximab) should be injected.

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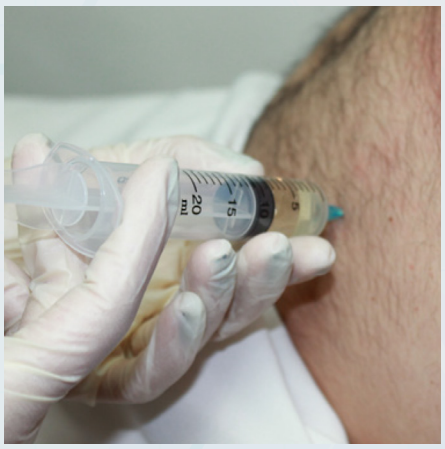

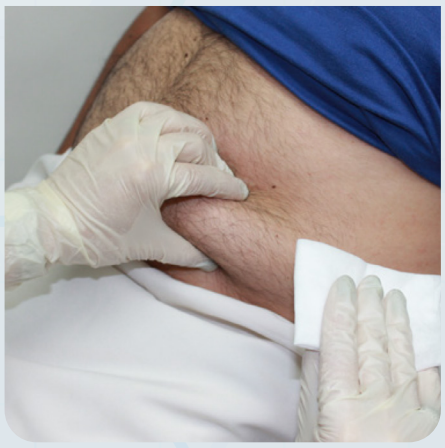

Perform the injection

- Pinch the skin of the abdomen with one hand to create a skin fold: this will facilitate the injection.
- Insert the injection needle into the skin fold with the other hand, using a sterile technique.
- Release the skin fold and apply pressure on the syringe, slowly injecting MabThera SC into the subcutaneous tissue.
- **MabThera SC should be administered over approximately 5–7 minutes.**
- Using the palm of the hand to depress the plunger can help to maintain a constant flow rate.
- Ensure the full content of the syringe is injected into the subcutaneous tissue.
- After application, the injection site may be covered with a dressing, as per locally approved protocol.

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Inform the patient that they may leave

The patient should be obsrved for **at least 15 minutes** following MabThera SC adimistration. A longer period of observation may be appropriate in patients with an increased risk of hypersensitivity reactions. If the patient is not receiving any further treatment after the MabThera SC injection, and if the patient is not presenting any adverse reaction to the injection, the patient may leave the clinic.

Many patients experience some side effects at or around the MabThera SC injection site. These local side effects include pain, swelling, bruising, bleeding, skin redness, itching and rash.
The patient should be instructed to contact their doctor immediately if the following symptoms happened: breathing difficulties, tongue or throat swelling, vomiting or palpitations, as they could be indicative of an allergic reaction.

*MabThera SC 1400 mg is indicated in adults for non-Hodgkin's lymphoma (NHL) only:

- For the treatment of previously untreated patients with stage III-IV follicular lymphoma (FL) in combination with chemotherapy.
- As maintance therapy for the treatment of patients with FL responding to induction therapy.
- For the treatment of patients with CD20-positive diffuse large B-cell NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisolone) chemotherapy.

The recommended dosage is a fix dose of 1,400 mg, irrespective of the patient's body surface area.

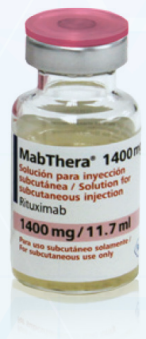
If you have any further questions, please refer to the Product Information, or contact your local Roche representative.

Please make sure that you select the correct MabThera® formulation.

SUBCUTANEOUS INJECTION

For use in non-Hodgkin´s Lymphoma ONLY*†

MabThera 1,400 mg solution for subcutaneous injection



Withdraw directly from the vial and administer by subcutaneous injection

Check for the specific MabThera SC packaging characteristics before use:

1. Red labelling: **'For subcutaneous use only', 'Solution for subcutaneous injection' and 'SC'**
2. Pink 'flip-off' cap

INTRAVENOUS INFUSION

For use in all MabThera-approved indications†

MabThera 100 mg concentrate for solution for infusion.
MabThera 500 mg concentrate for solution for infusion.

Dilute with 0.9% NaCl or 5% glucose and administer by intravenous infusion

† Please refer to the Summary of Product Characteristics for further information or contact your local Roche representative.

Healthcare professionals should report any adverse events, which are suspected to be associated with the use of Mabthera, to: **cac.farmacovigilancia@roche.com.**

"Material created by Roche"

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