MABTHERA® (RITUXIMAB®)

A comparison card to differentiate between the two formulations of MabThera® (subcutaneous and intravenous).

This leaflet has been produced by Roche for physicians, nurses and pharmacists for the safe and efficient use of MabThera® solution for subcutaneous injection (referred to as MabThera® SC) in patients with CLL and NHL

Please refer to the approved package insert for further information or contact your local Roche representative

MabThera®
Rituximab
CENTRAL TO SUCCESS

MabThera SC, **1,400 mg** is indicated in adults for **Non-Hodgkin's Lymphoma (NHL)**

- Monotherapy in patients with CD20-positive follicular non-Hodgkin's lymphoma (stage III–IV) who have relapsed after, or failed to respond to, chemotherapy.
- Treatment of previously untreated patients with CD20-positive follicular non-Hodgkin's lymphoma (stage III–IV) with high tumour burden in combination with CVP or CHOP
- Maintenance therapy of patients with relapsed or refractory CD20-positive follicular nonHodgkin's lymphoma (stage III–IV) who have responded to induction therapy with CHOP with or without rituximab
- Treatment of patients with CD20-positive diffuse large B-cell non-Hodgkin's lymphoma (DLBCL) in combination with standard CHOP (8 cycles of cyclophosphamide, doxorubicin, vincristine and prednisone).
- Mabthera 1,400 mg is only for subcutaneous use in NHL
- The recommended dosage is a fixed dose of **1,400 mg** irrespective of the patient's BSA

Important Reminder

For more information about MabThera SC

- **Send email: acrra.medinfo@roche.com**

To report an adverse event

- **Roche Drug Safety: global.irt_sahubtcs@roche.com**
- **Tel: +233 5543004426**

For other pharmacovigilance related matters, please email

- **accra.drug_safety@roche.com**

For Product complaints, please email

- **accra.product_qualitycomplaints@roche.com**

MabThera
Rituximab
CENTRAL TO SUCCESS

Solutions for subcutaneous injection

Guide to supply, storage, handling and administration of Mabhera subcutaneous formulations

Supply, storage and handling of MabThera® SC

How is MabThera® SC is supplied?

- Each carton contains one glass vial.
- Each vial contains a sterile, non-pyrogenic and preservative-free solution (extractable volume is equivalent to one dose for administration to the patient) of: — 13.4 ml (1,600 mg) for CLL — 11.7 ml (1,400 mg) for NHL
- 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.

– The excipients are:

- Recombinant human hyaluronidase (rHuPH20): this is an enzyme used to increase the dispersion and absorption of co-administered drugs when administered subcutaneously. It allows the injection of larger volumes via the subcutaneous route.
- Other excipients: L-histidine, L-histidine hydrochloride monohydrate, α,α-trehalose dihydrate, L-methionine, polysorbate 80 and water for injections. – The pH of the solution is between 5 and 6

How MabThera® SC should be stored?

- Keep the vial in the outer carton to protect MabThera® SC from light.
- Store MabThera® SC in a refrigerator (2-8 °C). DO NOT FREEZE.
- Check the expiry date on the outer carton.

Please refer to the approved package insert for further information.

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 colour 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 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

MabThera® Rituximab CENTRAL TO SUCCESS

How to administer MabThera® SC: Step-by-step guide

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 containing chemotherapy.

• 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.

1. 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.

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.

MabThera® Rituximab CENTRAL TO SUCCESS

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 should be injected:
— 11.7 ml (1,400 mg) for NHL

4. 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 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.

5. Inform the patient that they may leave

- The patient should be observed for at least 15 minutes following MabThera® SC administration. 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 with 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, induration, bleeding, skin redness, itching and rash.

- The patient should be instructed to contact their doctor immediately if the following symptoms occur: breathing difficulties, tongue or throat swelling, vomiting or palpitations, as they could be indicative of an allergic reaction

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Tel: +(233) 302 774752 . For adverse event reporting, please send an email to **global.irt_sahubtcs@roche.com** or call +(233) 554304426.
For product complaints, please send an email to **accra.product_qualitycomplaints@roche.com**. For Medical Information Requests,
please send an email to **accra.medinfo@roche.com**

For FDA reporting kindly send an email to :drug.safety@fdaghana.gov.gh

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