Please make sure that you select the correct MabThera® (rituximab) formulation and strength

SUBCUTANEOUS INJECTION

MabThera 1400 mg
ONLY FOR USE IN NHL*

Pink flip-off cap

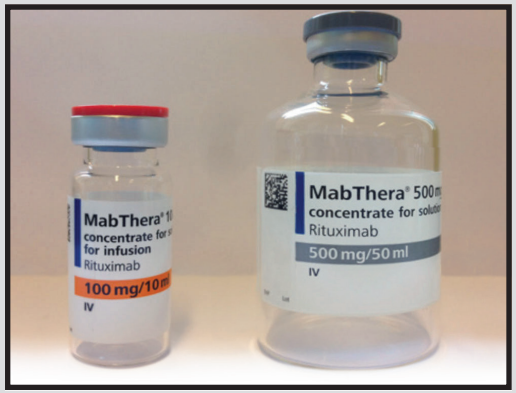
Withdraw directly from vial and administer by subcutaneous injection

Check for the specific MabThera SC packaging characteristics before use:

Red labelling: '**Only for subcutaneous use**', '**solution for subcutaneous injection**' and '**subcutaneous**'

INTRAVENOUS INFUSION

MabThera 100 mg concentrate for solution for infusion
MabThera 500 mg concentrate for solution for infusion
For use in all MabThera-approved indications*



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

MabThera SC is not indicated as once-weekly monotherapy in patients with relapsed/refractory follicular lymphoma.
*NHL = non-Hodgkin's lymphoma.
This material should be read in conjunction with the Summary of Product Characteristics (SmPC) which is available on www.medicines.ie and www.ema.europa.eu. See overleaf for how to use the peel-off part of the label.

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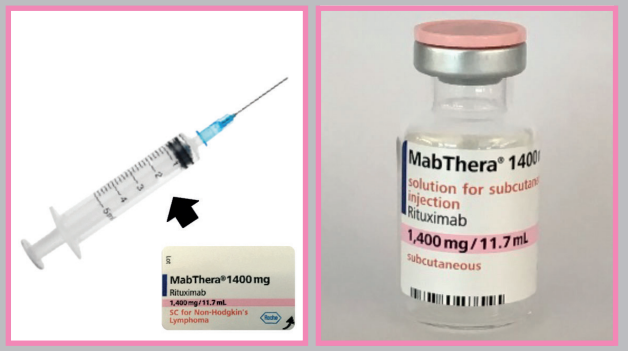
Use the peel-off part of the label to ensure the correct formulation and strength is administered to your patient, as illustrated below

MabThera 1400 mg solution for subcutaneous injection
ONLY FOR USE IN NHL*

1. The MabThera 1400 mg vial label has a removable part

2. Remove the peel-off part



3. Stick the peel-off part on to the syringe

Reporting of suspected adverse events or reactions

Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions (see details below). Where possible, healthcare professionals should report adverse events or reactions by brand name and batch number.

In the event of a suspected adverse event, please report it to:
Post: The Drug Surveillance Centre,
Roche Products (Ireland) Limited, 3004 Lake Drive,
Citywest, Naas Road, Dublin 24, Ireland.
Telephone: 00 353 (0)1 4690700
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at:
http://www.medicinesauthority.gov.mt/adrportal,
and sent by post or email to:
Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Email: postlicensing.medicinesauthority@gov.mt

Further Information

For additional electronic copies of this risk minimisation material, refer to the Malta Medicines Authority website [http://www.medicinesauthority.gov.mt/rmm] and download the required material. **Alternatively if you would like hard copies**, please contact Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24, Ireland by mail, telephone [00 353 (0)1 4690700], or email [ireland.drug_surveillance_centre@roche.com].

For further information about this medicine, please contact Medical Information at Roche Products (Ireland) Limited by telephone [00 353 (0)1 4690700] or email [Ireland.druginfo@roche.com].

This educational material is provided by Roche Products (Ireland) Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

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