IE Version 15.0.1
HPRA Approval Date: March 2017

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

SUBCUTANEOUS INJECTION

MabThera 1,400 mg
ONLY FOR USE IN NHL*†#

Pink flip-off cap

Withdraw directly from vial and administer by subcutaneous injection

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

Check for the specific MabThera SC packaging characteristics before use:
Red labelling: '**Only for subcutaneous use**', '**solution for subcutaneous injection**' and '**subcutaneous**'

Further information
To request further information about MabThera 1400mg solution for subcutaneous injection, please contact Medical Information at Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24 by mail, telephone (01 4690700), fax (01 4690791) or email (ireland.druginfo@roche.com). Electronic copies of this material are available on the HPRA website at www.hpra.ie. Additional hard copies of this material can be requested from Roche by email (ireland.dra@roche.com), telephone (01 4690700) or fax (01 4690791).

*NHL = non-Hodgkin's lymphoma.
† MabThera SC is not indicated as monotherapy in patients with stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after chemotherapy.
# Please refer to the relevant MabThera Summary of Product Characteristics (available on www.medicines.ie) for further information.

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

MabThera 1,400 mg solution for subcutaneous injection
ONLY FOR USE IN NHL

1. The MabThera 1,400 mg vial label has a removable part

2. Remove the peel-off part

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

This material is provided by Roche Products (Ireland) Limited as a licence requirement for this medicine and forms part of the MabThera Risk Management Plan.

Reporting of suspected adverse events: Reporting suspected adverse events 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 events (see details below). **In the event of a suspected adverse event, please report it to:** The Drug Surveillance Centre, Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700, Fax: (01) 4690793, Email: ireland.drug_surveillance_centre@roche.com**. Alternatively, suspected adverse reactions should be reported to:** The Pharmacovigilance Section, The Health Products Regulatory Authority (HPRA), Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2. Telephone: (01) 6764971, Fax: (01) 6762517, Email: medsafety@hpra.ie, website: www.hpra.ie.
As MabThera is a biologic medicine, healthcare professionals are encouraged to report adverse events by brand name, batch number and expiry date.

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