



PRODUCTS WITH ADDITIONAL RISK MINIMIZATION MEASURES (RMM)

Rituximab (MabThera)

Introduction:

Rituximab (MabThera) is indicated for the underlisted.

- Non-Hodgkin's Lymphoma (NHL)
- Chronic Lymphocytic Leukaemia (CLL)
- Rheumatoid Arthritis
- Granulomatosis with polyangiitis and microscopic polyangiitis
- Pemphigus vulgaris

MabThera is available in two formulations for the respective indications listed below

- MabThera solution for subcutaneous injection (MabThera SC): Non-Hodgkins Lymphoma ONLY
- MabThera concentrate for solution for infusion: All MabThera approved indications

Safety Concern:

Administration Route Error: Risk of administration error between subcutaneous and intravenous rituximab formulations

Additional Risk Minimization Measure (aRMM)

Educational materials for healthcare professionals with the objective to educate them about use of the SC formulations to reduce the likelihood of accidental product substitution and ensure that the SC formulation is injected correctly.

The educational material comprises of a comparison card which focuses on package differentiation, and step by step guide which aims to educate on correct injection technique.

Ghana Mabthera 1400 mg comparison card for SC formulation - <http://fdaghana.gov.gh/img/Ghana%20Mabthera%201400%20mg%20comparison%20card%20for%20SC%20formulation.pdf>>

Ghana Mabthera 1400 mg step-by-step guide for SC formulation - <http://fdaghana.gov.gh/img/Ghana%20Mabthera%201400%20mg%20step-by-step%20guide%20for%20SC%20formulation.pdf>