

ATC codes: L01FA01

Indication	Chronic lymphocytic leukaemia or small lymphocytic lymphoma	ICD11 code: 2A82.0
INN	Rituximab	
Medicine type	Biological agent	
List type	Complementary	
Additional notes	Including quality-assured biosimilars	
Formulations	Parenteral > General injections > IV: 100 mg per 10 mL in 10 mL vial ; 500 mg per 50 mL in 50 mL vial	
EML status history	First added in 2015 (TRS 994) Changed in 2019 (TRS 1021)	
Sex	All	
Age	Adolescents and adults	
Therapeutic alternatives	The recommendation is for this specific medicine	
Patent information	Main patents have expired but secondary patents might remain active in some jurisdictions. For more information on specific patents and license status for developing countries visit www.MedsPal.org  Read more about patents. 	

Tags

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Summary of evidence and Expert Committee recommendations

The Committee noted the correspondence from the European Society for Medical Oncology (ESMO) requesting recognition of biosimilars of rituximab and trastuzumab on the EML. The Committee agreed that quality-assured biosimilars of these monoclonal antibodies represent an opportunity for expanding affordable access to cancer medicines for health systems. To help improve access, the Committee recommended the current listing for intravenous rituximab on the EML should indicate that quality-assured biosimilars of rituximab should also be considered as essential medicines. In addition, the Expert Committee recommended that WHO continue to facilitate access to biosimilars through the Prequalification programme and WHO Collaborative Registration Procedure.

[Expert Committee report !\[\]\(b4eeff342f60cc7bcd67d869b4fedca2_img.jpg\)](#)