

Stabilis



Rituximab































Tradename

Mabthera	Argentina, Australia, Austria, Belgium, Chile, Colombia, Croatia, Denmark, Ecuador, Egypt, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, Morocco, Netherlands, New Zealand, Norway, Peru, Poland, Portugal, Romania, Saudi Arabia, Spain, Sweden, Switzerland, Tunisia, Turkey, United Arab Emirates, Venezuela
Novex	Argentina
Reditux	Chile, Peru
Rigetuxer	Mexico
Rituxan	Canada, Japan, United States of America
Rituximab	New Zealand
Rixathon	Belgium, France, Germany, Great Britain, Spain, Switzerland
Truxima	Belgium, Canada, France, Germany, Great Britain, Spain, United States of America






Stability in solutions

		10 mg/ml	23-25°C		21			4676
		10 mg/ml	23-32°C		21			4708
		10 mg/ml	2-4°C		28			4016
		10 mg/ml	25°C		15			4016
PE		1 mg/ml	2-8°C		31			4040
PP		1 mg/ml	2-8°C		31			4040
POF		1 mg/ml	2-4°C		28			4016
POF		1 mg/ml	2-8°C		180			3323
POF		1 mg/ml	25°C		15			4016
POF		1 mg/ml	4°C		90			2881
POF		4 mg/ml	2-4°C		28			4016
POF		4 mg/ml	25°C		15			4016

		4 mg/ml	4°C		90			2881
		120 mg/ml	2-8°C		28			2825
		120 mg/ml	30°C		24			2825
		1 >> 4 mg/ml	2-8°C		30			4740
		1 >> 4 mg/ml	<30°C		24			4740
		1 >> 4 mg/ml	2-8°C		24			4740
		1 >> 4 mg/ml	25°C		12			4740








Factors which affect stability

	40°C			2881 3323
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Compatibility

			
		Rituximab Temocilline	2296



Route of administration























References

	Type	Publication
2296	Manufacturer	Témocilline (Negaban®) - Résumé des caractéristiques du produit Eumédica 2017
2825	Journal	Mueller C, Dietel E, Heynen S, Nalenz H, Goldbach P, Mahler H, Schmidt J, Grauschopf U, Schoenhammer K. Physico-chemical Stability of MabThera Drug-product Solution for Subcutaneous Injection under In-use Conditions with Different Administration Materials. Int J Pharm Compound 2015 ; 19, 3: 261-267.
2881	Poster	Jaccoulet E, Guirao S, Morand K, Astier A, Paul M. Stabilité d'un anticorps monoclonal d'intérêt thérapeutique après reconstitution: le rituximab. SFPO Congress 2009
3323	Journal	Paul M, Vieillard V, Jaccoulet E, Astier A. Long-term stability of diluted solutions of the monoclonal antibody rituximab. Int J Pharm 2012 ; 436, 1-2: 282-290.

4016	Journal	Vieillard V, Paul M, Ibrahim T, Astier A. Extended stability of the rituximab biosimilar CT-P10 in its opened vials and after dilution and storage in polyolefin bag. Ann Pharm Fr 2017 ; 75, 6: 420-435.
4040	Journal	Lamanna W.C, Heller K, Schneider D, Guerrasio R, Hampl V, Fritsch C, Schiestl M. The in-use stability of the rituximab biosimilar Rixathon®/Riximyo® upon preparation for intravenous infusion. J Oncol Pharm Practice 2017 ;25,2: 269-278
4676	Poster	Borišek R, Šmid I. Assessing the stability of Sandoz rituximab biosimilar after exposure to out-of-fridge conditions for 21 days. EAHP Congress Vienna 2022
4708	Journal	Borišek R, Mischo A, Šmid I. Study of the Stability of Sandoz Rituximab Biosimilar Rixathon®/Riximyo® When Subjected for up to 21 Days to Ambient Storage. Drugs R D 2022 ; 22,3: 225–234
4740	Manufacturer	MabThera 500 mg concentrate for solution for infusion. Summary of Product Characteristics Updated 07-Oct-2021 Roche Products Limited 2021



Dictionary

 Anticancer drug	 Injection
 Tradename	 Stability in solutions
 Container	 Molecule
 Concentration	 Temperature
 Storage	 Duration of stability
 Biosimilar	 Conflicting data
 References	 Glass
 None	 Protect from light
 Day	 Not specified
 Partially used vials	 Polyethylene
 Sodium chloride 0,9%	 Polypropylene
 Polyolefine	 Polypropylen Syringe
 Light	 Hour
 Not specified	 Glucose 5%
 Factors which affect stability	 Induces
 Degradation	 Compatibility
 Compound	 Solvent
 Unspecified incompatibility	 Incompatible
 Route of administration	 Intravenous infusion
 References	 Dictionary