

Stabilis



Trastuzumab



Nekomercijalni

Besintex	Čile, Peru
Herceptin	Argentina, Australija, Austrija, Belgija, Brazil, Čile, Danska, Egipat, Ekvador, Finska, Francuska, Grčka, Iran, Irska, Island, Italija, Japan, Kanada, Kolumbija, Luksemburg, Mađarska, Malezija, Maroko, Meksiko, Nizozemska, Njemačka, Norveška, novi Zeland, Peru, Poljska, Portugal, Rumunjska, S A D, Saudijska Arabija, Španjolska, Švedska, Švicarska, Turska, Ujedinjeni Arapski Emirati, Velika Britanija
Herzuma	Belgija, Francuska, Kanada, Njemačka, S A D, Španjolska, Velika Britanija
Kanjinti	Argentina, Belgija, Njemačka, Španjolska, Velika Britanija
Ogivri	Australija, Belgija, Peru, Španjolska
Ontruzant	Španjolska
Trastuzumab Baxter	novi Zeland
Trazimera	Argentina, Velika Britanija



Stabilizacija rješenja

		21 mg/ml	2-8°C	?	48			3077
		21 mg/ml	23-27°C		3			4271
		21 mg/ml	4°C		30			4493
		21 mg/ml	2-8°C		28			3113
		21 mg/ml	2-5°C		90			4191
		mg/ml	<30°C	?	24			3077
		? mg/ml	2-8°C	?	30			3077
		0,2 & 4 mg/ml	2-8°C	?	42			4754
		0,24 mg/ml	2-8°C		7			4163
		0,24 mg/ml	30°C		24			4163
		0,4 mg/ml	2-8°C	?	28			4194
		1 mg/ml	2-8°C	?	28			4194

PVC		3,84 mg/ml	2-8°C		7				4163
PVC		3,84 mg/ml	30°C		24				4163
PVC		4 mg/ml	2-8°C		28				4194
PE		mg/ml	<30°C		24				3077
PE		? mg/ml	2-8°C		30				3077
PE		0,32 mg/ml	2-8°C		28				4271
PE		0,32 mg/ml	23-27°C		28				4271
PE		0,56 mg/ml	2-8°C		28				4271
PE		0,56 mg/ml	23-27°C		28				4271
PE		4 mg/ml	2-8°C		28				4271
PE		4 mg/ml	23-27°C		28				4271
PP		mg/ml	<30°C		24				3077
PP		? mg/ml	2-8°C		30				3077
PP		0,4 mg/ml	2-8°C		28				3258
PP		0,4 mg/ml	2-8°C		28				4194
PP		0,4 mg/ml	25°C		28				3258
PP		0,8 mg/ml	4°C		180				3343
PP		1 mg/ml	2-8°C		28				4194
PP		2,4 mg/ml	4°C		180				3343
PP		4 mg/ml	2-8°C		28				3258
PP		4 mg/ml	2-8°C		28				4194
PP		4 mg/ml	25°C		28				3258
POF		21 mg/ml	2-8°C		63				4649
POF		0,2 & 4 mg/ml	2-8°C		42				4754
POF		0,24 mg/ml	2-8°C		7				4163
POF		0,24 mg/ml	30°C		24				4163
POF		0,3 mg/ml	2-8°C		21				4649
POF		0,3 mg/ml	30°C		48				4477
POF		0,8 mg/ml	18-22°C		180				3386
POF		0,8 mg/ml	2-8°C		180				3386
POF		0,8 & 2,4 mg/ml	2-5°C		90				4191
POF		0,8>>4 mg/ml	2-8°C		76				4649
POF		0.3 mg/ml	2-8°C		28				4396

POF	▲	0.3 mg/ml	30°C		28				4396
POF	▲	0.8 & 2.4 mg/ml	25°C	?	3				4493
POF	▲	0.8 & 2.4 mg/ml	4°C	?	90				4493
POF	▲	2,4 mg/ml	18-22°C		180				3386
POF	▲	2,4 mg/ml	2-8°C		180				3386
POF	▲	3,8 mg/ml	2-8°C		35				4477
POF	▲	3,84 mg/ml	2-8°C		7				4163
POF	▲	3,84 mg/ml	30°C		24				4163
POF	▲	3.8 mg/ml	2-8°C		28				4396
POF	▲	3.8 mg/ml	30°C		28				4396
EVA	▲	0,2 & 4 mg/ml	2-8°C	?	42				4754
	∅	120 mg/ml	2-8°C		48				3647
	∅	120 mg/ml	2-8°C	?	28				2975
	∅	120 mg/ml	<30°C		6				3647
	∅	120 mg/ml	2-8°C	?	28				2975
	▲	0,3 mg/ml	2-8°C		21				4649
	▲	0,8>>4 mg/ml	2-8°C		76				4649
?	▲	0.4 >> 4 mg/ml	2-8°C	?	28				3849



Stabilnost mješavine

PVC	▲	2.3 mg/ml	30°C		Pertuzumab : 2.7 mg/ml	24		3366
PVC	▲	2.3 mg/ml	5°C	?	Pertuzumab : 2.7 mg/ml	24		3366
POF	▲	1.5 mg/ml	30°C		Pertuzumab : 1.5 mg/ml	24		3366
POF	▲	2.3 mg/ml	30°C		Pertuzumab : 2.7 mg/ml	24		3366
POF	▲	2.3 mg/ml	5°C	?	Pertuzumab : 2.7 mg/ml	24		3366



Stabilizacijski faktor

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Kompatibilnosti

		Trastuzumab		3077
		Trastuzumab : 1,5 & 2,3 mg/ml Pertuzumab : 1,5 & 2,7 mg/ml		3366
		Trastuzumab Temocilline		2296
		Trastuzumab		3077



način davanja lijeka



Bibliografija

	Vrsta	Publikacija
2296	Laboratorija	Témocilline (Negaban®) - Résumé des caractéristiques du produit Eumedica 2017
2975	Plakat	Nalenz H, Schoenhammer K, Dietel E, Heynen S.R, Grauschopf U, Mahler H.C. In-Use stability of herceptin for subcutaneous injection with different administration materials. ESCP 2014 2014
3077	Laboratorija	Trastuzumab (Herceptin®) – Summary of Product Characteristics Roche 2019
3113	knjiga	Herceptin Compendium Suisse des médicaments 2010
3258	Časopis	Kaiser J, Krämer I. Physicochemical Stability of Diluted Trastuzumab Infusion Solutions in Polypropylene Infusion Bags. Int J Pharm Compound 2011 ; 15, 6 : 515-520.
3343	Plakat	Vieillard V, da Silva R, Astier A, Paul M. Physicochemical stability of diluted trastuzumab solutions stored 6 months at 4°C. ECOP Congress, Budapest, Hungary 2012
3366	Časopis	Kwong Glover Z.W, Gennaro L, Yadav S, Demeule B, Wong P.Y, Sreedhara A. Compatibility and stability of pertuzumab and trastuzumab admixtures in i.v. infusion bags for coadministration. J Pharm Sci 2012 ; DOI 10.1002 / jps.23403
3386	Časopis	Paul M, Vieillard V, Da Silva Lemos R, Escalup L, Astier A. Long-term physico-chemical stability of diluted trastuzumab. Int J Pharm 2013 ; 448: 101-104.
3647	Laboratorija	Trastuzumab (Herceptin® 600 mg for subcutaneous injection) - Summary of Product Characteristics Roche 2019
3849	Časopis	Pabari R.M, Ryan B, Ahmad W, Ramtoola Z. Physical and structural stability of the monoclonal antibody, trastuzumab (Herceptin®), intravenous solutions. Curr Pharm Biotech 2013 ; 14, 2: 220-225.

4163	Časopis	Nalenz H, K?pf E, Dietel E. Prolonged In-Use Stability of Reconstituted Herceptin in Commercial Intravenous Bags. Int J Pharm Compound 2018 22;5:417-423
4191	Časopis	Vieillard V, Astier A, Paul M. Extended stability of a biosimilar of trastuzumab (CT-P6) after reconstitution in vials, dilution in polyolefin bags and storage at various temperatures. GaBI Journal 2018
4194	Časopis	Kim S.J, Lee J.W, Kang H.Y, Kim S.Y, Shin Y.K, Kim K.W, Oh J.S, Lim K.J, Kim J.Y. In-Use Physicochemical and Biological Stability of the Trastuzumab Biosimilar CT-P6 Upon Preparation for Intravenous Infusion. Bio Drugs 2018 32;619-625
4271	Časopis	Yun J, Kim J, Chung J, Hwang S-J, Park S-J. Extended Stability of Reconstituted and Diluted SB3 (Trastuzumab Biosimilar) Assessed by Physicochemical and Biological Properties Adv Ther 2019
4396	Časopis	Lueras A, Polozova A, Asbury D, Hippenmeyer J, Litowski J, Goss M, Breslin P, Crampton S. c GaBI Journal 2020 ; 9, 1:
4477	Časopis	Crampton S, Polozoxa A, Asbury D, Lueras A, Breslin P, Hippenmeyer J, Litkowski J.,Goss M. Stability of the trastuzumab biosimilar ABP 980 compared to reference product after intravenous bag preparation, transport and storage at various temperatures, concentration and stress conditions. GaBI Journal 2020 ; 9, 1: 5-13.
4493	Časopis	Le Guyader G, Vieillard V, Paul M. Physicochemical stability study of MYL-1401O, a biosimilar of trastuzumab, following a transient temperature excursion. J Oncol Pharm Practice 2020
4649	Časopis	Davies L, Milligan K, Corris M, Clarke I, Dwyer P, Lee S-E, Teraoka J, Crouse-Zeineddini J, Hippenmeyer J. Extended stability of the trastuzumab biosimilar ABP 980 (KANJINTI™) in polyolefin bags and elastomeric devices. GaBI Journal 2021 ; 10, 4
4754	Časopis	Weiser S, Burns C, Zartler E Physicochemical stability of PF-05280014 (trastuzumab-qyyp; Trazimera™), a trastuzumab biosimilar, under extended in-use conditions. J Oncol Pharm Practice 2023 ;29,3:



rječnik

	lijek protiv karcinoma		injekcija
	Nekomercijalni		Stabilizacija rješenja
	Kontejner		Molekula
	koncentracija		temperatura
	Konzerviranje		Trajanje stabilnosti
	biosimilar		proturječni podaci
	Bibliografija		čaša
	čista voda za injektiranje		nespecifičan
	sat		Zaštićeno od svjetlosti
	dan		voda ppi i bakteriostaticna
	djelomično korištene boce		polivinilklorid
	natrijumkorid 0,9%		svjetlost
	polietilen		polipropilen
	Sa i bez svjetlosti		poliolefin
	etilvinilacetat		špric polipropilen
	nijedan		šprica polikarbonata
	Poliizoprenski elastomer		nespecifičan
	Stabilnost mješavine		sredstvo za rastapanje
	molekula		Stabilizacijski faktor
	glukoza 5%		izaziva
	Degradacija		Kompatibilnosti
	Kompatibilan		Neodređena nespojivost
	inkompatibilan		način davanja lijeka
	intravenozna infuzija		subkutani
	Bibliografija		rječnik