

Physico-chemical data for the product below in a ready-to-use solution

Active ingredient		Trade name		Supplier	
Pharmaceutical form			If powder, please indicate solvent(s)		

Final container	Diluent	Manufacturer	Type of packaging*	Storage temperature*	Light protection? (please tick)		Shelf life (days/nights, hours)	Concentration range (mg/mL)**
					Yes	No		
Infusion bag	0.9%NaCl	Baxter	ViaFlo®	2-8° C				
				8-25° C				
		Fresenius Kabi	FreeFlex®	2-8° C				
				8-25° C				
			FreeFlex® Plus	2-8° C				
				8-25° C				
	KabiPac®	2-8° C						
		8-25° C						
	B.Braun	EcoFlac®	2-8° C					
			8-25° C					
	5%Glucose	Baxter	ViaFlo®	2-8° C				
				8-25° C				
Fresenius Kabi		FreeFlex®	2-8° C					
			8-25° C					
B.Braun		EcoFlac®	2-8° C					
			8-25° C					

*: All the **packaging types** listed are proprietary products authorised in Denmark as of 1 April 2017. Only the fields for the packaging types used in the stability test may be filled in.

** : Based on the current edition of (1) Danish Pharmaceuticals Standards (*Danske LægemiddelStandarder (DLS)*), the section on: "Storage of pharmaceuticals > Storage conditions" and (2) Guideline issued by the Danish Health Authority (*Sundhedsstyrelsen*): "Guideline for drawing up summary of product characteristics for proprietary medicinal products for human consumption", para 6.4: "Special storage conditions". In both guidelines, the following wording is used: "To be stored at 2-8° C", indicated in the table as: "2-8° C" and "Do not store above 25° C", indicated in the table as: "8-25° C".

***: The **concentration range** of the pharmaceutical in the ready-to-use solution within which the indicated physico-chemical stability applies. Reference is made to the current version of: *Guideline of the European Commission: "A Guideline on Summary of Product Characteristics", para 6.3: "Shelf life". The Rules governing Medicinal Products in the European Union, Volume 2C, Notice to Applicants. Example: "The concentration range within which the physico-chemical stability for substance xxx has been demonstrated at 0.04 to 4 mg/ml."*

The Qualified Person (QP) of the supplier hereby guarantees the accuracy of the above by its signature:

Date

Name and title of QP

QP signature