




## Data regarding stability, compatibility and disposal of cytostatic solutions as to aseptic preparation

Name of the drug product	Holoxan solution 2g/ 50 ml	Holoxan 200 mg dry substance	Holoxan 500 mg dry substance	Holoxan 1 g dry substance	Holoxan 2 g dry substance	Holoxan 3 g dry substance
active ingredient (API)	Ifosfamide			Ifosfamide		
Concentration of active ingredient if necessary in the reconstituted solution	40 mg/ml	40 mg/ ml (200 mg Ifo + 5 ml water for injection)	38,5 mg/ ml (500 mg Ifo + 13 ml water for injection)	40 mg/ ml (1 g Ifo + 25 ml water for injection)	40 mg/ ml (2 g Ifo + 50 ml water for injection)	40 mg/ ml (3 g Ifo + 75 ml water for injection)
storage temperature	2°C - 8°C			< 25 °C		
light protection	no			no		
shelf life	6 months			60 months		
density	1,015 g/ml			4 % aqueous solution 1,0100 g/ml		
pH value	4,8 - 6,5			4,5 – 6,5		
carrier solution for infusions	Fructose solution 5 %	Glucose solution 5 %ig	NaCl solution 0,9 %	Ringer's lactate solution	water for injection	
concentration in carrier solution				individual dosing		
physico-chemical stability in carrier solution	increase of degradation resp. decrease of content: 0.01 % per day at < 8°C/ 0.1 % per day at 21°C/ 0.2 % per day at 26°C					
light protection of prepared solution	<b>recommendation:</b> apply within 24 h, because preparation does not contain any preservative					
physico-chemical stability after first opening	no reconstituted solution: increase of degradation resp. decrease of content: 0.01 % per day at < 8°C/ 0.1 % per day at 21°C/ 0.2 % per day at 26°C					
stability of the product after non-proper storage	<b>recommendation:</b> apply within 24 h, because preparation does not contain any preservative					
applied stopper material	disposal bromobutyl elastomer latex-free					
disposal/combustion/chemical deactivation	disposal according to each current national legal requirement for special waste German disposal code 180105D1					
contact with aluminum-containing materials/ contact with antioxidants	not known					



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