

ophtha futur® octa | deca



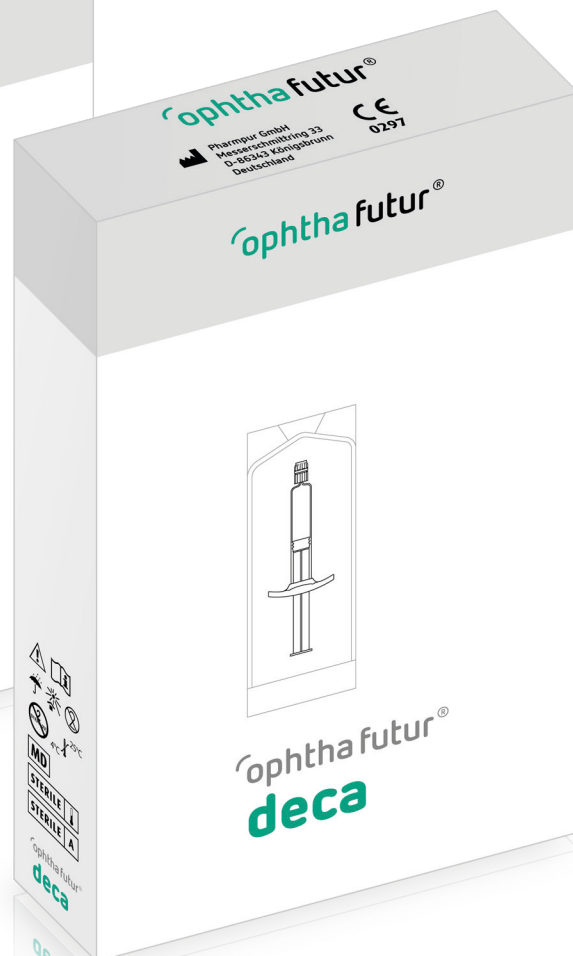
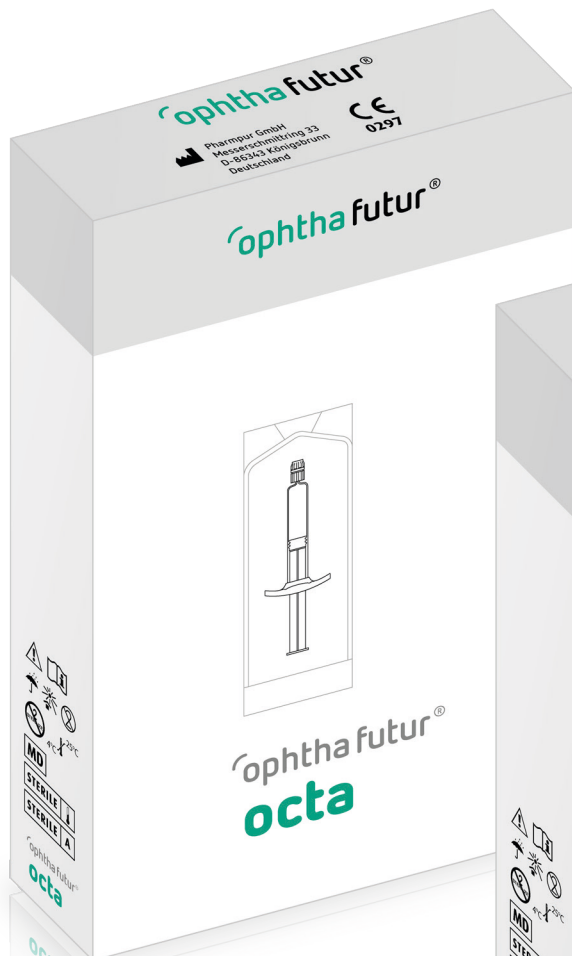
High patient and product safety

Multi-step proven & tested ultra-purification process

Safe, biocompatible, sterile, endotoxin-free products

Cyclo-Olefin Copolymers (COC) syringes

36 months shelf life



ophthafutur[®] octa | deca

technical data-sheet

Product Name	ophthafutur® octa			ophthafutur® deca			
Active compound	perfluorooctane			perfluorodecalin			
Physical and Chemical Parameters							
Sum Formula	C ₈ F ₁₈			C ₁₀ F ₁₈			
Refractive Index n _D ²⁰	1.27			1.31			
Density (20 °C)	1.77 g/ml			1.93 g/ml			
Vapor pressure (at 37°C)	8.8 kPa			3.4 kPa			
Compound Surface Tension	14 mN/m			19 mN/m			
Interfacial Tension against Water	54 mN/m			53 mN/m			
Chemical Control							
Fluorination level	100 %			100 %			
H-value	≤ 10 ppm			≤ 10 ppm			
Additionally controlled Impurities (GC/MS)							
• concentration of C-H components	< 10 ppm			< 10 ppm			
• 1H-PFO content	< 1 ppm			n.a.			
• Perfluorofurane content	< 0.4%			n.a.			
Microbial control							
Product Sterility ensured by	Sterile Filtration			Sterile Filtration			
Outer Surface Sterility ensured by	Steam Sterilization			Steam Sterilization			
Bacterial Endotoxins ¹	≤ 0.2 EU/ml			≤ 0.2 EU/ml			
¹ LAL test acc. to EP 2.6.14/USP <85>							
Biocompatibility acc. to DIN EN ISO 10993							
Cytotoxicity ²	Non cytotoxic			Non cytotoxic			
Sensitization ³	Non sensitizing			Non sensitizing			
Irritation ⁴	Non irritating			Non irritating			
² Growth inhibition test of serum extract acc. to DIN EN ISO 10993-5:2009							
³ Murine Local Lymph Node Assay (LLNA) acc. to DIN EN ISO 10993-10:2010							
⁴ Acute eye-irritation on rabbits acc. to DIN EN ISO 10993-10:2010 Appendix B							
Cell Toxicity (%)	0	8	14	36	72	87	92
H-value (ppm)	≤ 10	175	350	700	1,400	2,100	2,800
Menz D-H, Feltgen N, Menz H, et al. How to ward off retinal toxicity of perfluorooctane and other perfluorocarbon liquids? Invest Ophthalmol Vis. Sci. 2018; 59: 4841-4846.							
Presentation	Filling Volume	Container	Sterile Barrier		Shelf Life		
ophthafutur® deca	5 ml / 7 ml	Vial	Pouch		36 months		
ophthafutur® deca	5 ml / 7 ml	Syringe	Pouch		36 months		
ophthafutur® octa	5 ml / 7 ml	Vial	Pouch		36 months		
ophthafutur® octa	5 ml / 7 ml	Syringe	Pouch		36 months		