

ophtha futur® octa | deca



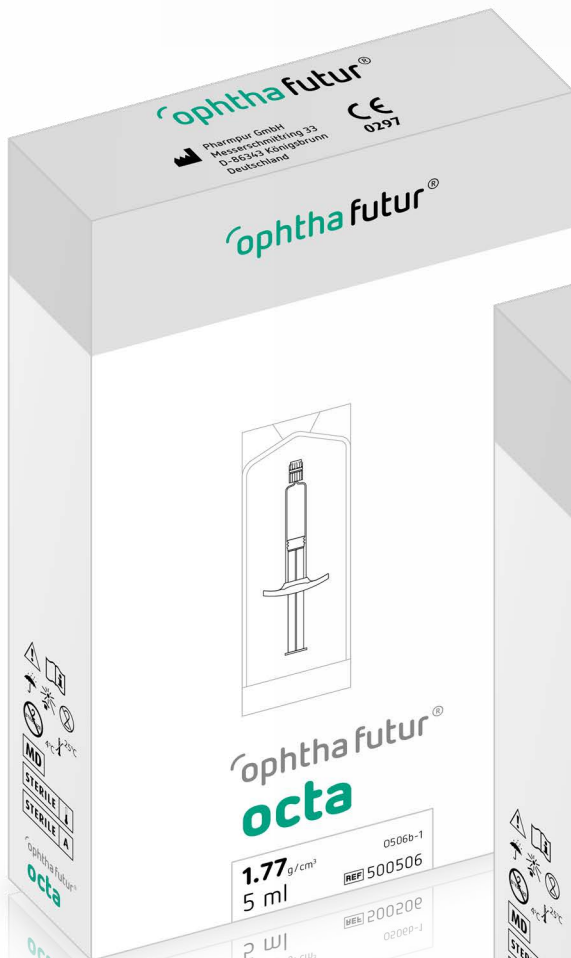
High patient and product safety

Multi-step proven & tested ultra-purification process

Safe, biocompatible, sterile, endotoxin-free products

Novel high performance polymer syringes (HPPS)

36 months shelf life



ophthafutur[®] octa | deca

technical data-sheet

Product Name

Active compound

ophthafutur[®] octa
perfluorooctane

ophthafutur[®] deca
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 (%)

| | | | | | | | |
|---------------|------|-----|-----|-----|-------|-------|-------|
| H-value (ppm) | 0 | 8 | 14 | 36 | 72 | 87 | 92 |
| | ≤ 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 |