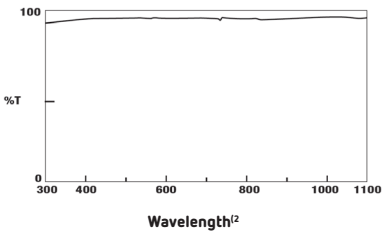


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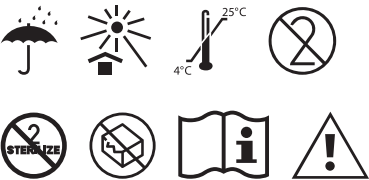


Curve of Spectral Transmittance⁽¹⁾



(1) Curve of Spectral Transmittance | Spektrale Transmissionskurve | Courbe de Transmittance Spectrale | Curva de Transmisión Espectral | Curva di Trasmissione Spettrale | Curve van de Spectrale Doorlaatbaarheid | Křivka Spektrální Propustnosti | Spektrális Áteresztési Görbe | Krzywa Transmitancji Widmowej | КРИВАЯ СПЕКТРАЛЬНОГО КОЭФФИЦИЕНТА ПРОПУСКАНИЯ

(2) Wavelength | Wellenlänge | Longueur d'onde | Longitud de onda | Lunghezza d'onda | Golflengte | Vlnová Délka | Hullámhossz | Długość Fali | Длина волны (нм)



Ophthafutur Deca**Ophthafutur Octa****Composition and Characteristics:**

Ophthafutur Deca: 100% fluorinated perfluorocarbon containing isomers of perfluorodecalin (95 – 100%), perfluorocyclohexyl-butane and perfluorohydrindane. Ophthafutur Deca is a clear fluid of high specific gravity (1.93 g/cm³) with a refractive index of 1.31.

Ophthafutur Octa: 100% fluorinated perfluorocarbon containing isomers of perfluorooctane (> 95 %), perfluoroheptane and perfluorononane. Ophthafutur Octa is a clear fluid of high specific gravity (1.77 g/cm³) with a refractive index of 1.27.

Ophthafutur Deca and Ophthafutur Octa are non-toxic due to the 100% fluorination, which results in the complete absence of C-H structures. It is free of preservatives, chemical inert and does not decompose in the eye.

Indications:

Surgical aid

- to unfold and reposition the retina in cases of retinal detachment/PVR/PDR, giant tears, ocular traumata
- for laser coagulation and cryotherapy
- for lifting of subluxated lenses and foreign bodies from the vitreous cavity

Administration and dosage:

The extend of the vitrectomy and the necessary dose of Ophthafutur Deca / Ophthafutur Octa differ in each specific case and have to be determined intraoperatively by the ophthalmic surgeon. Foreign bodies and subluxated lenses may be underflushed with Ophthafutur Deca / Ophthafutur Octa after vitrectomy and are then lifted to the pupillary level by the perfluorocarbon, where they can be removed safely. Ophthafutur Deca / Ophthafutur Octa has to be completely removed by aspiration at the end of the operation.

Contraindications:

There are no contraindications known.

Adverse reactions:

It cannot be excluded that, due to its high gravity and low viscosity, Ophthafutur Deca / Ophthafutur Octa may generate alterations of the retina if present over a long period of time. Care should be taken to avoid any sub-retinal penetration of the product.

Interactions:

If a subsequent silicone oil ocular endotamponade is planned, Ophthafutur Deca / Ophthafutur Octa has to be removed before the instillation of silicone oil as completely as possible to avoid alterations of the silicone oil. Other interactions are not known.

Warnings and precautions:

Ophthafutur Deca / Ophthafutur Octa

- is for intraocular use only
- must not be reused
- must not be resterilized

The sterility of the product is only guaranteed if the pack is unopened and undamaged. The product must not be used after the expiration date. Opened product should not be kept for later use. The use of non-sterile or re-sterilized perfluorocarbons or multiple use of a vial/syringe can lead to cross-contamination or serious health impairment of the patient. The vitreous cavity must not be overfilled with Ophthafutur Deca / Ophthafutur Octa. Before unfolding the retina with Ophthafutur Deca / Ophthafutur Octa, all traction on the retina should be loosened so that the additional weight of the perfluorocarbon may not induce iatrogenal retinal detachment or fissures of the retina. The rubber closure of the vial is no septum. No specific clinical data on the results of the long-term influence of heavy perfluorocarbons on the human retina exist. Therefore Ophthafutur Deca / Ophthafutur Octa should be completely removed by aspiration at the end of the operation as necrotizing of the retinal vessels or any other damage of the retina by the high specific gravity in combination with low viscosity of the perfluorocarbon cannot be excluded. Gas or silicone oil can be subsequently used if a prolonged tamponade of the retina is necessary. If remnants of Ophthafutur Deca / Ophthafutur Octa remain in front of the retina in the form of mobile drops, they may influence the refraction and thus change the visual acuity temporarily.

Storage:

Store the product at room temperature (store dry at 4 °C – 25 °C) and protect against sunlight.

Presentation and sterilization:

Ophthafutur Deca / Ophthafutur Octa is supplied sterile in a glass vial and syringe delivering 5 and 7 mL.

Product sterilization: Sterile filtration.

Exterior sterilization: Steam sterilization.

Manufacturer :

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