

ophtha futur®

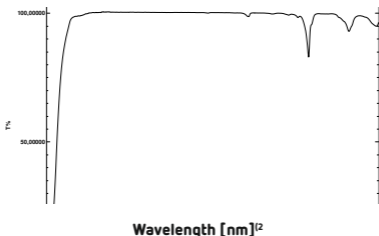
sil 1000

sil 2000

sil 5000



Curve of Spectral Transmittance¹



- (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)



Information as of: | Stand der Information: | Informations en date de: | Información de: | Informazioni valide al: | Informatie per: | Informace ke dni: | A tájékoztató összeállításának időpontja: | Informacja począwszy od: | Информация по состоянию на:
06/2016

Ophthafutur Sil 1000**Ophthafutur Sil 2000****Ophthafutur Sil 5000****Composition and Characteristics:**

Ophthafutur Sil 1000 / 2000 / 5000: consists of ultrapurified, sterile silicone oil (polydimethylsiloxane) with a viscosity of 1000 – 1500 / 1700 – 2300 / 5000 – 5900 mPas. Ophthafutur Sil 1000 / 2000 / 5000 is clear, colourless, odourless and has a refractive index of 1,403 – 1,405.

Indications:

Ophthafutur Sil 1000 / 2000 / 5000 is used as an ocular endotamponade in severe cases of retinal detachment with, e.g. solid proliferative vitreo-retinopathy, traumatic detachment, giant tears, as well as other detachments of the retina which cannot be treated with other forms of therapy.

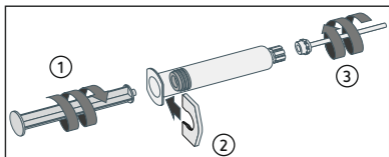
The use of silicone oil in cases of central foramina with detachment or in cases of severe diabetic retinopathies is presently discussed.

Administration and dosage:

If the syringe is to be emptied manually, the piston (1) placed in the sterile pouch has to be screwed into the stopper. The plastic finger flange (2) included in the sterile pack can be clipped on the finger flange of the syringe in order to support manual emptying. If an injection system for silicone oil is used, care must be taken to ensure proper mounting according to the direction for use of the tubing set and the used injection system.

To remove potentially contained air, the syringe has to be positioned with the tip straight up. The closure cap is removed from the syringe by careful rotation and the needed cannula is fixed on the Luer Lock adapter of the syringe (3). Only now the air bubble is removed completely. The injection of silicone oil should be started slowly. By all means care has to be taken to firmly fix the tubing system used on the Luer Lock of the syringe. If necessary fixation aids have to be used. The scale on the label is a dosing aid.

The selection of patients, of the operation methods, of the dose and the duration of the endotamponade are the sole responsibility of the ophthalmic surgeon.



Contraindications:

Ophthafutur Sil 1000 / 2000 / 5000 should not be applied after implantation of silicone intraocular lenses.

Warnings and precautions:

The product should only be used by physicians having the necessary knowledge about handling of this product.

Ophthafutur Sil 1000 / 2000 / 5000 is only intended for surgery of the posterior segment of the eye. Do not reuse or re-sterilize Ophthafutur Sil 1000 / 2000 / 5000.

The use of non-sterile or re-sterilized silicone oil or multiple use of a syringe can lead to cross-contamination or serious health impairment of the patient. The expiry date is based on the storage conditions below. Do not use an opened and/or damaged sterile packaging. Do not overfill the posterior segment with Ophthafutur Sil 1000 / 2000 / 5000. The occurrence of corneal decompensation, cataract, or secondary glaucoma has been reported. Also the occurrence of emulsification with remarkable decrease of the visual acuity has been observed. The clinical experience has shown that the silicone oil should be removed with stabilization of the disease or with occurring complications. During combined application of perfluorocarbon liquids (PFCL) and silicone oil emulsification have been described. Therefore PFCL have to be removed from the eye before silicone oil is injected. On removal of the silicone oil in the post-operative phase, during which the acuity neither increases nor further decreases again, the final operative result can be improved.

Storage:

Ophthafutur Sil 1000 / 2000 / 5000 should be stored at room temperature (store dry at 4 °C – 25 °C) and protected against light and frost.

Presentation and sterilization:

Ophthafutur Sil 1000 / 2000 / 5000 is supplied STERILE in a glass syringe delivering 10 mL. Product sterilization: Dry heat sterilization. Exterior sterilization: Steam sterilization.

Manufacturer:

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