

SPECIAL INSTRUCTIONS		BAUSCH & LOMB	APPROVALS / DATE
ARTWORK SET AT 100% OF ACTUAL SIZE	COATING PER SPECIFICATION	PACKAGING/GRAPHIC ENL. LWTF 424/425 INDUSTRIAL PARK, WATERFORD, IRELAND TEL: 353 51 859791 FAX: 353 51 859115	PROG/PPV _____ REV/ISS _____ REG AFF _____
THE INFORMATION LISTED BELOW MUST APPEAR ON ALL VENDOR PROOF'S (COLORKEYS, MATCHPOINTS/CHROMALING) OR THEY WILL BE REJECTED		DA _____ DCI NUMBER _____ DATE _____	
PLACED PICTURES:			
AW # 4032701	DESCRIPTION: 1300 mPa.s Silicone Oil / 5700 mPa.s Silicone Oil DPU	SPEC. NO. N/A	
NUMBER OF PRINTING PLATES 1	TOTAL NUMBER OF PMS COLORS 1	PAGE 1 OF 1	
PMS COLORS		PROCESS MATCH COLORS	
1. Pantone Process Black C			

Bausch & Lomb
Oxane® 1300/5700
Silicone Oil

EN Product Information

COMPOSITION 1ml contains highly pure sterile silicone oil, 1000-1500mPas or 5000-2900mPas. Refractive index = 1.40.

INDICATIONS: Oxane® is used for intraocular tamponade in severe cases of retinal detachment, e.g. severe detachment with massive proliferative vitreoretinopathy, traumatic detachment, giant tears as well as other retinal detachments, which cannot be treated with other forms of therapy. The use of silicone oils in cases of central foramina with detachment or in cases of severe diabetic retinopathies is at present under discussion. **CONTRAINDICATIONS:** Intraocular lenses made from silicone can be opacified by silicone oil. Therefore, silicone oil should not be applied in eyes with silicone IOLs. Other contraindications are not known. **METHOD OF USAGE AND DOSAGE:** Oxane® is injected intracocularly in a dose to be determined by the ophthalmic surgeon. The selection of patients, the choice of surgical procedure and the length of the indwelling period of the silicone oil in the eye are the sole responsibility of the ophthalmic surgeon. **PRECAUTIONS OF USE:** For ocular use only. Do not reuse; do not resterilize; do not use if sterile barrier is breached; verify the expiry date; do not overfill the post-use segment with Oxane®. Oxane® is free from preservatives, do not use for more than one patient. Left-over fluid must be disposed. **WARNINGS:** Heavy liquids like all types of fluorocarbon liquids have to be removed completely from the vitreous cavity before silicone oil can be filled into the eye. Following the use of silicone oils that were not highly purified, the occurrence of corneal decompensation, cataract, secondary glaucoma and emulsification has been reported. Although the causal relationship with the purity of the silicone oil has not yet been established, the incidence of these complications appears to be lower following the use of highly pure silicone oil. The duration of the indwelling period of the silicone oil in the eye must be determined by the treating physician. Some reports indicate a period of use of more than two years. It has been shown that on removal of the silicone oil in the post-operative phase, during which the visual acuity neither increases nor further decreases again, the final operative result can be improved. **INTERACTION WITH OTHER SUBSTANCES:** Presently, no interactions between Oxane® and other substances are known. **STORAGE INSTRUCTIONS:** Store Silicone Oil below 25°C. **PRESERVATION AND STERILIZATION:** Oxane® is supplied STERILE in a glass syringe delivering 10ml. Sterilization: product and outer surface simultaneously in a steam sterilizer. **ADVERSE REACTIONS:** Adverse reactions and/or potentially sight-threatening complications that may be reasonably regarded as Oxane®-related and that were not previously expected in nature, severity or degree of incidence should be reported to a Bausch & Lomb representative.

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Artwork History			
4032701	Previous artwork revision updated for rebranding and new artwork number assigned	PD	04th Apr '06
4032701 @ A	Updated to replace Mpas with mPa.s on Lionel's request	PD	25th May '06
4032701 @ B	Updated to remove Mpas in front of word silicone oil throughout document on Lionel request. Also change precautions to correct wording from ISO 15798 (do not use if sterile barrier is breached) & include new symbol.	PD	27th Jun '06
4032701 @ C	Updated Brand sub brand & descriptor to identify standards & adapted to new keyline	PD	11th Oct '06
4032701 @ D	Address noted as Rochester address and Waterford as Manufacturer Updated TM/R mark sentence to change requested from legal trademark to include or its affiliates	PD	21/12/2006

BAUSCH & LOMB CONTROLLED DOCUMENT SIGNATURE PAGE

Document Name : 4032701

Document Title : Oxane 1300/5700 DFU

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