



**MeniLAB is the first cleaning, disinfecting* and prion elimination ** solution
Specifically designed for decontaminating RGP diagnostic trial contact lenses**

FOR PRACTITIONER USE ONLY

Composition:

Active chlorine solution qs 0,5% or 5 000 ppm of active chlorine
Purified water qs 100%
Packaging: 250 ml CE 0483

For more information on MeniLAB contact:-

Technical Support Team at
David Thomas Contact Lenses Ltd
Tel: +44 (0) 1604-646216
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Email: peterrolfe@davidthomas.com

**cf disinfecting tests :*

*antiviral efficacy (Université médicale de Nancy MDT, référence : CEN / TC 216 / N 98 , AFNOR NFT 72 -180)
antibactériale and antifungal activity (MENICON PHARMA référence : ISO / CD 14729 stand alone test),
anti-acanthamoeba activity (Institut de bactériologie institut, Strasbourg medical University;*

Menicon co.,Ltd / microbiology and immunology department from Leicester UK).

*** cf anti-prion activity (N°277111 report june2002, C.E.A. / SPI BIO / MENICON*

DAVID THOMAS Contact Lenses Ltd
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5 years research about Prions

NCTA Inactivation treatments evaluation:

After 5 years of several and intensive researches conducted by the Neurovirology laboratory of the French CEA (Commissariat à l'Énergie Atomique) led by Professor Dominique Dormont, with the partnership of SPI-BIO, Menicon Pharma and Menicon Europe, final results of the study 277111

“Evaluation of the efficacy of protocols for disinfection of rigid gas-permeable contact lenses through inactivation and/or removal of Transmissible Spongiform Encephalopathy (TSE, Prions) agents” were published in *“J.Fr.Ophthalmol”*. 2003; 26, 3,233-239. (Copies available upon request)

In practice, the study demonstrates, by using 7 groups of Menicon care regimens, the efficacy of Sodium Hypochlorite solution containing a low concentration of active chlorine (0,5%) in the inactivation against prion of grinded Menicon Z lenses contaminated by a laboratory TSE strain in 5 minutes.

Based on these results, the use after each trial of RGP lens of the now available MeniLAB 0,5% solution alone can reduce a hypothetical prion contamination from 7,5 logs in 5 minutes as well as the referenced NaClO solution with 2% active chlorine in 1 hour.

Modalities of use in contact lens practice are described below:

INSTRUCTION FOR USE

1. After removing the Trial lens, clean using MeniCare Plus cleaning solution, rubbing for at least 20 seconds and then thoroughly rinse with MeniCare Plus solution.
3. Fill a vial or lens case with MeniLAB 0.5% solution and leave lens to soak for 5 minutes.
4. After 5 minutes carefully rinse for 15 seconds using a MeniCare Plus multi-purpose solution.
5. Store lens in MeniCare Plus solution until next used.
6. Before fitting, rinse again with MeniCare Plus solution (repeat section 4).

NB. Every treatment must be recorded (traceability document)

Providing the Trial lens is undamaged, free from deposits and within specification tolerances, and has been cleaned and maintained as per the above instructions, it may be used indefinitely.

PRECAUTIONS

- Do not use for Soft lenses.
- The soaking time in MeniLAB 0.5% solution must not exceed one hour (may cause discolouration).
- It is essential to rinse the lenses abundantly with MeniCare multipurpose solution after soaking in MeniLAB 0.5% solution.
- DO NOT put the solution directly in the eye. Avoid splashing on to clothing.
- Do not swallow.
- Store at room temperature (<25°).
- Use within 3 months after opening. Noting the expiry date.
- Never use tap water for contact lens rinsing.

TRACEABILITY

A traceability document should be completed to record date, patients name, batch number, lens parameters, trial set used, etc. (see example).

Note: All DTCL trial lenses are subject to the above decontamination procedure.

Single patient use (Mono-Use) trial lenses are available. All trial lenses are strictly NOT FOR RESALE.

Note: Safety Data Sheet (EC regulations 91/155/EEC / COSHH) is available upon request.

For further information contact Technical Support on +44(0)1604-646216 or email peterrolfe@davidthomas.com

DAVID THOMAS

GP TRIAL SET DISINFECTION RECORD SHEET

| Parameters ro / øT / bvp | Batch No. | MeniLAB Procedure Date / Signature | MeniLAB Procedure Date / Signature | MeniLAB Procedure Date / Signature | MeniLAB Procedure Date / Signature |
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- Each trial lens should receive a number. Note parameters and lot number.
- After using trial lens: Note parameters, lot number, date of treatment & operator signature.

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