

BVI

Enhancing Target Tissue Visualization High Density Solution Of Trypan Blue

MONOBLUE NafX (No Air Fluid Exchange)



MONOBLUE NafX Introduction

A high density solution of ultra pure Trypan blue (0.15%) providing enhanced dyeing efficiency and visualization of ILM¹ and ERM².

DESCRIPTION:

MONOBLUE NafX is a purified Trypan blue high density isotonic sterile and apyrogenic solution presented in a single dose syringe with 0.75ml of 0.15% solution.

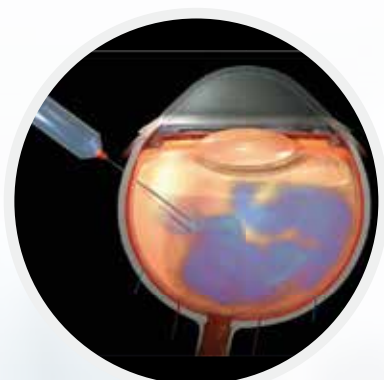
Mannitol and Deuterium oxide (heavy water) are two key components of the high density MONOBLUE NafX solution, preventing dispersion of the Trypan blue in the vitreous cavity and favoring its layering on the target tissues.

The syringe and the connector are packaged in a pouch that is externally sterile to allow its use in the operating theatre. Each box contains 5 pouches (syringes+ connector) and 5 tuberculin syringes sterilized by autoclaving.

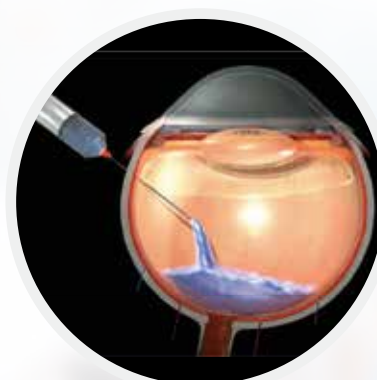
MONOBLUE NafX Advantages

HIGH DENSITY MONOBLUE NAFX SOLUTION

- Makes staining procedures of ILM and ERM easier and safer
- Suppresses risks linked to air fluid exchange steps
- Shortens duration of vitreoretinal surgery
- Enables an effective staining of ILM and ERM within 30 to 60 seconds



Injection of Standard Trypan blue solution



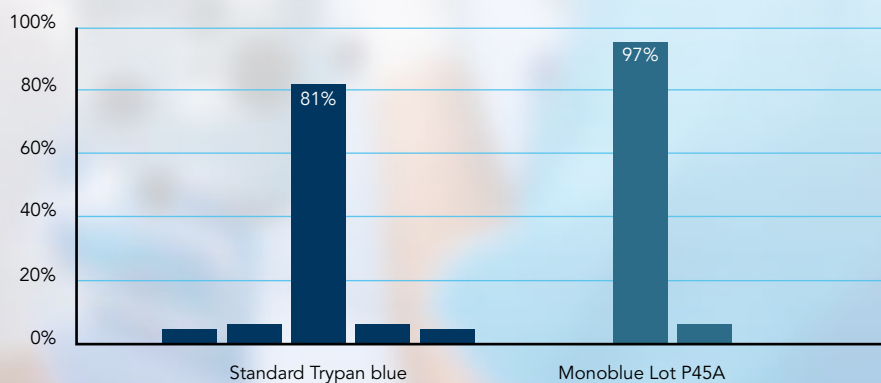
Injection of MONOBLUE NafX Directly onto ILM and ERM

AN ULTRA-PURE STAINING AGENT

Enhanced safety and tolerability

- O-tolidine*: not detectable**
- Preservative free
- Latex free
- Endotoxin: ≤ 0.2 UE/ml

Comparative Purity Data on Different Solutions of Trypan blue***



¹ Internal Limiting Membrane.

² EpiRetinal Membrane.

*Toxicity concern may arise with high concentration of impurities like O-tolidine and byproducts.

**Detection limit: less than 0.1 ppm.

***Data In House for Gas Chromatography.

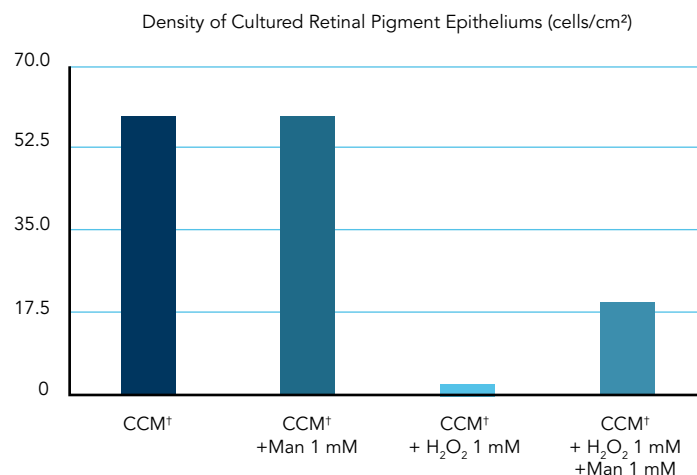
PROTECTIVE EFFECT OF MANNITOL

Mannitol is a free radical scavenger with anti-oxidant effect

Mannitol is a key component of MONOBLUE NafX, it protects retinal pigment epithelium cells from the oxidative effect of H_2O_2 ^{3,4}.

Density of retinal pigment epithelium cells in:

- CCM[†] + H_2O_2 1 mM: 3 cells/cm²
- CCM[†] + H_2O_2 1 mM + Mannitol 1 mM: 18 cells/cm²
- CCM[†] + Mannitol 1 mM: 59 cells/cm²

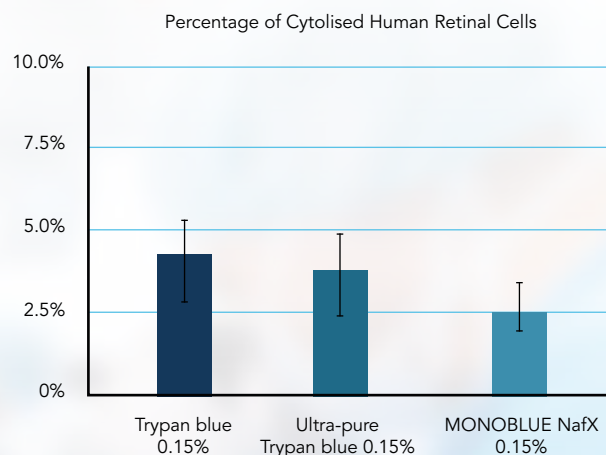


ENHANCED TOLERABILITY

Improved protection of human retinal cells

The following table presents the percentage of the cytolysed human retinal cells percentage after 5 minute^{5,6} exposure to either 0.15% Trypan blue solution, 0.15% ultra-pure Trypan blue solution or MONOBLUE NafX 0.15%.

- Trypan blue 0.15%: 4.1 ± 1.2% cytolysed cells
- Ultra-pure Trypan blue 0.15%: 3.5 ± 1.2% cytolysed cells
- MONOBLUE NafX 0.15%: **2.5 ± 0.8% cytolysed cells**



THE INJECTION SYSTEM GUARANTEES A CONTROLLED ADMINISTRATION

- Prefilled syringe of 0.15% Trypan blue + luer/luer connector + tuberculin syringe
- MONOBLUE NafX syringe is packed with a long-barrel tuberculin syringe for additional improvement of the injection, and the distribution of Trypan blue on target areas
- MONOBLUE NafX is smoothly delivered onto the vitreoretinal membranes thanks to the tuberculin syringe. It prevents retinal injury due to jet-stream or due to possible subretinal leakage of the staining solution.



3 Liu JH and a. Therapeutic effects and mechanisms of action of Mannitol during H_2O_2 -induced oxidative stress in human retinal pigment epithelium cells. J Ocul Pharmacol Ther. 2010 Jun;26(3): 249-57.

4 Gupta LY, Marmor MF. Mannitol, dextromethorphan, and catalase minimize ischemic damage to retinal pigment epithelium and retina. Arch Ophthalmol. 1993 Mar;111(3):384-8.

5 Arcad Study on Human Retinal Cells. 2011, Nov.

6 Lei H, Velez G, Cui J, Samad A, Maberley D, Matsubara J, Kazlauskas A. N-acetyl cysteine suppresses retinal detachment in an experimental model of proliferative vitreoretinopathy. Am J Pathol. 2010 Jul;177(1):132-40.

† Cells Culture Medium.

Clinical Applications References

STAINING FOR INTERNAL LIMITING MEMBRANE PEELING

- 1 Mackenzie SE, Gandorfer A, Rohleder M, Schumann R, Schlottmann PG, Bunce C, Xing W, Gregor Z, Charteris DG. Ultrastructure and retinal imaging of internal limiting membrane: a clinicopathologic correlation of trypan blue stain in macular hole surgery. *Retina*. 2010 Apr;30(4):655-61.
- 2 Perrier M, Sébag M. Trypan blue-assisted peeling of the internal limiting membrane during macular hole surgery. *Am J Ophthalmol*. 2003 Jun;135(6):903-5.

STAINING FOR EPIRETINAL MEMBRANE PEELING

- 1 Balayre S, Gicquel J, Dighiero P. Selective ERM Staining During Vitrectomy Using Trypan Blue. Poster Ever 2004.
- 2 Feron EJ, Veckeneer M, Parys-Van Ginderdeuren R, Van Lommel A, Melles GR, Stalmans P. Trypan blue staining of epiretinal membranes in proliferative vitreoretinopathy. *Arch Ophthalmol*. 2002 Feb;120(2):141-4.

MONOBLUE NafX Safety Facts

- ISO 13485-2016 certified company
- Unique advantage with the addition of Mannitol
- No case of cytotoxicity over 15 years of production⁷
- More than 1.000.000 syringes of Trypan Blue solutions placed on the market
- Unique purification process
- European legal manufacturer

Safety First For Our Product Line



ARCIOLANE

Fractionated and Purified
Silicone Oil



ARCALINE - ARCOTANE

Heavy Liquids for
Ophthalmic Surgery



OP'COVER

Corneal Protection



ARCEOLE

Ready-to-Use Set
of Ophthalmic Gas

⁷ ARCAD_PMS-PMCF_05_Report_V0 No case of cytotoxicity reported.

FOR COMPLETE PRODUCT INSTRUCTIONS, PLEASE REFER TO THE IFU SUPPLIED WITH THE PRODUCT

<https://www.bvimedical.com/customers-support/>