FOR THE USE OF A REGISTERED MEDICAL PRACTITIONER OR A HOSPITAL OR A LABORATORY ONLY.

BIO-BLUE

FOR INTRAOCULAR USE AS AN ADJUNCT TO OPHTHALMIC SURGERY
TRYPAN BLUE OPHTHALMIC SOLUTION 0.6 MG / ML

1. Description:

BIO-BLUE is a sterile, pyrogen free solution of Trypan Blue, a biocompatible intraocular solution used during ophthalmic surgery.
BIO-BLUE is a selective tissue staining agent for use as a medical aid in ophthalmic surgery. It is frequently used in eyes with mature cataracts, poor red fundus reflex or narrow pupils. **BIO-BLUE** does not contain preservative.
BIO-BLUE has a pH of between 7.3 to 7.6 and its osmolality is 270-400 mOsm/kg.
Trypan Blue has a molecular formula of $C_{34}H_{24}N_6Na_4O_{14}S_4$ and a molecular weight of 960.8

2. Composition:

Each ml contains:
Trypan Blue .....0.6 mg
Isotonic Aqueous Base .....q. s.

3. How supplied:

BIO-BLUE is supplied in a single use, prefilled, disposable glass syringe with a Luer-lock fitting delivering 1.0 ml of solution. Prefilled syringe is packed in a medical grade blister pack. Each box contains one sterile syringe blister, two product traceability labels and one sterile single use 27G cannula (ETO sterilized). **BIO-BLUE** is terminally sterilized using steam.

4. Indications:

BIO-BLUE is indicated for use as an aid in Ophthalmic surgery by staining the anterior capsule of the lens.

5. Mode of action:

BIO-BLUE selectively stains connective tissue structures in the human eye such as the anterior lens capsule of the human crystalline lens.
BIO-BLUE is intended to be applied directly onto the anterior lens capsule, staining any portion of the capsule which comes in contact with the dye. Excess dye is washed out of the anterior chamber. The dye does not penetrate the capsule, permitting visualization of the anterior capsule in contrast to the non-stained lens cortex and inner lens material.

6. Directions for use:

Under strict aseptic conditions open the blister at the marked end and take out the prefilled syringe. Hold the luer lock. Twist the cap carefully with the other hand in anti-clockwise direction and remove it. Hold the syringe and insert the cannula, turn the cannula in clockwise direction to lock it as tightly as possible so that the cannula may not come off while injecting the product. Gently push plunger rod to expel air bubbles from syringe tip and cannula.

7. Contraindications:

BIO-BLUE is contraindicated when a non-hydrated (dry state), hydrophilic acrylic intraocular lens (IOL) is planned to be inserted into the eye because the dye may be absorbed by the IOL and stain the IOL.

8. Adverse reactions:

Adverse reactions reported following use of **BIO-BLUE** include discoloration of high-water content hydrogen intraocular lenses (see Contraindications) and inadvertent staining of the posterior lens capsule and vitreous face. Staining of the posterior lens capsule or staining of the vitreous face is generally self-limited, lasting up to one week.

9. Warning and Precautions:

- The solution is for intraocular use only and not for IM/IV injection.
- For single use only.
- Check the integrity of packaging and glass container before use.
- Do not use if the package is opened or damaged.
- It is recommended that after injection all excess **BIO-BLUE** should be immediately removed from the eye through irrigation of the anterior chamber.
- Do not use if floating particles are found.
- **BIO-BLUE** may lead to allergic reactions in hypersensitive patients.
- Do not re-use cannula and/or syringe.
- Do not re-sterilize by any method.
- Do not use the product after its expiry date.
- To be used by an authorized medical practitioner only.
- Keep away from sunlight.
- All the accessories (cannula/syringe) provided to use the product, product itself and its primary packaging are considered as biological waste after usage of the product. It should not be reused in any case and further disposed as per the applicable guideline of the country. If reused, it may lead to any biological reactions including but not limited to inflammation, infection, injury or any unknown clinical condition.

Use in specific population:

- **Pregnancy:** There are no adequate and well-controlled studies in pregnant women. Trypan blue should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.
- **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when trypan blue is administered to a nursing woman.
- **Pediatric Use:** The safety and effectiveness of trypan blue have been established in pediatric patients. Use of trypan blue is supported by evidence from an adequate and well-controlled study in pediatric patients.
- **Geriatric Use:** No overall differences in safety and effectiveness have been observed between elderly and younger patients.

Non-clinical Toxicology

Trypan Blue is carcinogenic in rats. Wister/Lewis rats developed lymphomas after receiving subcutaneous injections of 1% trypan blue dosed at 50mg/kg every other week for 52 weeks (total dose approximately 1,00,000 fold-the maximum recommended human dose of 0.75 mg per injection in 60 kg person, assuming total absorption)

10. Storage conditions:

Store between 2°C to 35°C.

11. Expiration date:

The expiration date is 36 months from the date of manufacturing.
BIO-BLUE must be used prior to the expiry date printed on the package.

12. Reporting of serious incidents:

Users should report serious incident with medical device information to the manufacturer and/or to the national competent authority depending on national practice.

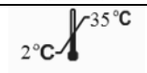
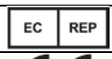
Once corrective (or other) action is identified from manufacturer, hospital administrators, medical practitioners and other health-care professionals, and USER representatives responsible for the maintenance and the safety of MEDICAL DEVICEs, can take the necessary steps. Such steps should, where practicable, be taken in co-operation with the MANUFACTURER.

For the purposes of Medical Devices Vigilance System in member states are represented by appointed National Competent Authorities, their vigilance contact points being listed on the European Commission web site: http://ec.europa.eu/growth/sectors/medical-devices/contacts/index_en.htm.

13. Electronic IFU

Any national version has been translated from the core English text. In case of discrepancy, English text shall be considered final. For the latest version of the IFU, please refer the English version of electronic IFU. The content of this document is subject to change without prior notice.

14. Explanation of international symbols:

SYMBOL	EXPLANATION
	Consult Instructions for Use.
	Use-by date (YYYY / MM)
	Batch Number
	Date of manufacture
	Manufacturer
	Medical Device
	Caution
	Temperature limit.
	Keep away from sunlight.
	Do not use if package is damaged.
	Do not re-sterilize.
	Do not re-use.
	Sterilized using steam.
	European Representative
	CE2460 certified product (For BIO-BLUE PFS)
	CE0123 certified product (For Cannula)

biotech

FOR BIO-BLUE PFS:

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Mfg. Lic. No.: G/28/1622

EC REP

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Roscommon, Ireland.

CE 2460

FOR CANNULA:

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North Moons Moat, Redditch,
Worcestershire B98 9ND,
UNITED KINGDOM.

EC REP

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13581, Berlin, Germany

CE 0123

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