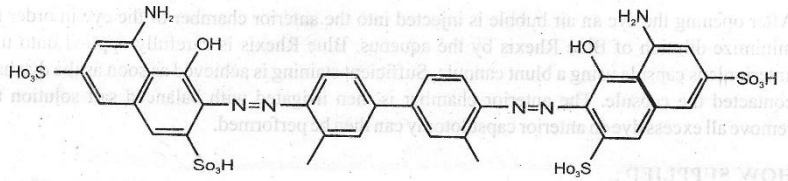
TRYPAN BLUE SOLUTION

Blue Rhexis

DESCRIPTION:
Blue Rhexis (Trypan Blue Solution) 0.06% is a sterile solution of trypan blue (an acid di-azo group dye). Blue Rhexis is a selective tissue staining agents for use as a medical aid in ophthalmic surgery.

Each mL of Blue Rhexis 0.06% contains: 0.6 mg trypan blue. The pH 6.8 -7.8.

The drug substance trypan blue has the chemical name 3,3'-[(3,3'-dimethyl-4,4'-biphenylylene) bis (azo)] bis (5-amino-4-hydrxy-2,7-naphthalenedisulfonic acid) tetra sodium salt, a molecular weight of 960.8, a molecular formula of $C_{34}H_{24}N_6Na_4O_{14}S_4$, and has the following chemical structure;



CLINICAL PHARMACOLOGY:
Blue Rhexis selectively stains connective tissue structures in the human eye such as the anterior lens capsule of the human crystalline lens.

Blue Rhexis is intended to be applied directly on 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.

INDICATION AND USAGE:
Blue Rhexis is indicated for use as an aid in ophthalmic surgery by staining the anterior capsule of the lens.

CONTRAINDICATIONS:
Blue Rhexis 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.

PRECAUTIONS:
General: It is recommended that after injection all excess Blue Rhexis be immediately removed from the eye by through irrigation of the anterior chamber.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:
Trypan blue is carcinogenic in rats. Wister/Lewis rats developed lymphomas after receiving subcutaneous injection of 1 % trypan blue dosed at 50 mg/kg every other week for 52 weeks (total dose approximately 1,250,000-fold the maximum recommended human dose of 0.06 mg per injection in a 60 kg person, assuming total absorption).

Trypan Blue was mutagenic in the Ames test and caused DNA strand breaks in vitro.

ADVERSE REACTIONS:
Adverse reaction reported following use of Blue Rhexis 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.

DOSAGE AND ADMINISTRATION CATARACT SURGERY:
Blue Rhexis is packaged in a 1 mL vial or 1 mL Syringe to which a blunt cannula has to attached.

After opening the eye an air bubble is injected into the anterior chamber of the eye in order to minimize dilution of Blue Rhexis by the aqueous. Blue Rhexis is carefully applied onto the anterior lens capsule using a blunt cannula. Sufficient staining is achieved as soon as the dye has contacted the capsule. The anterior chamber is then irrigated with balanced salt solution to remove all excess dye an anterior capsulotomy can then be performed.

HOW SUPPLIED:
Blue Rhexis 0.06% is supplied as follows:
1 mL of Blue Rhexis in a sterile single use Luer Lock, 1 mL glass syringe, rubber plunger stopper and tip cap with polypropylene plunger rod in a blister or 1mL in glass vials.

Storage:
Blue Rhexis is stored between 20°C and 25°C.

DOSAGE:
As directed by the physician.

Mfg.Lic.No.: G/28/1197

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STERILE

CE 2460

SYMBOL:

	See Information for use
	Do not reuse
	Do not resterilise
	Store in dry place
	Store between 20°C and 25°C
	Protect from direct Sunlight
	Do not use if package damaged
STERILE	Steam Sterilized
LOT	Batch code
	Date of Manufacture (YYYY-MM: Year-month)
	Use by (YYYY-MM: Year-month)
	Manufacturer
EC REP	European Representative

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