HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VISIONBLUE® safely and effectively. See full prescribing information for VISIONBLUE®.

VISIONBLUE® (trypan blue ophthalmic solution) 0.06%, for intraocular ophthalmic use
Initial U.S. Approval: 2004

----------INDICATIONS AND USAGE----------
VisionBlue® 0.06% is a diagnostic dye indicated for use as an aid in ophthalmic surgery by staining the anterior capsule of the lens. (1)

----------DOSAGE AND ADMINISTRATION---------
- Inject an air bubble into the anterior chamber;
- Carefully apply VisionBlue® 0.06% onto the lens capsule;
- Remove all excess dye from the anterior chamber. (2)

----------DOSAGE FORMS AND STRENGTHS--------
VisionBlue® (trypan blue ophthalmic solution) 0.06% in a single-patient-use syringe. (3)

----------CONTRAINDICATIONS----------
Insertion of a non-hydrated (dry state), hydrophilic acrylic intraocular lens (IOL). (4)

----------WARNINGS AND PRECAUTIONS----------
Excessive Staining: Excess VisionBlue® 0.06% should be removed from the eye immediately after staining. (5)

----------ADVERSE REACTIONS----------
Inadvertent staining of the posterior lens capsule and vitreous face. (6)

To report SUSPECTED ADVERSE REACTIONS contact Dutch Ophthalmic, USA at 1-800-75-DUTCH or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for PATIENT COUNSELING INFORMATION

Revised: 12/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the Full Prescribing Information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VisionBlue® 0.06% is indicated for use as an aid in ophthalmic surgery by staining the anterior capsule of the lens.

2 DOSAGE AND ADMINISTRATION

Cataract Surgery

VisionBlue® 0.06% is packaged in a single-patient-use syringe filled to a volume of 0.5 mL to which a blunt cannula has to be attached.

After opening the eye, an air bubble is injected into the anterior chamber of the eye in order to minimize dilution of VisionBlue® 0.06% by the aqueous. VisionBlue® 0.06% 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.

3 DOSAGE FORMS AND STRENGTHS

VisionBlue® (trypan blue ophthalmic solution) 0.06% is a clear, dark blue ophthalmic solution supplied in a 2.25 mL single-patient-use syringe filled to a volume of 0.5 mL.

4 CONTRAINDICATIONS

VisionBlue® 0.06% is contraindicated when a non-hydrated (dry state), hydrophilic acrylic intraocular lens (IOL) is planned to be inserted into the eye. The dye may be absorbed by the IOL and stain it.

5 WARNINGS AND PRECAUTIONS

5.1 Excessive Staining

It is recommended that after injection all excess VisionBlue® 0.06% is immediately removed from the eye by thorough irrigation of the anterior chamber.

6 ADVERSE REACTIONS

Adverse reactions reported following use of VisionBlue® 0.06% include discoloration of high water content hydrogen intraocular lenses *[see Contraindications (4)]* 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.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on the use of VisionBlue® 0.06% in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Systemic absorption of VisionBlue® 0.06% in humans is expected to be negligible following

injection and subsequent removal of the drug at the completion of surgical procedures. Adequate animal reproduction studies were not conducted with VisionBlue® 0.06%, however, trypan blue has been shown to be teratogenic in various animal models at doses 800-fold and greater than the maximum recommended human dose, based on body surface area (BSA).

Due to the negligible human systemic exposure when used as recommended, it is not expected that maternal use of VisionBlue® 0.06% will result in fetal exposure to the drug and risk of teratogenic effects.

Animal Data
Trypan blue is teratogenic in rats, mice, rabbits, hamsters, dogs, guinea pigs, pigs, and chickens. The majority of teratogenicity studies performed involve intravenous, intraperitoneal, or subcutaneous administration in the rat. The teratogenic dose is 50 mg/kg as a single dose or 25 mg/kg/day during embryogenesis in the rat. Normalized to BSA, these doses are approximately 1,600- and 800-fold the maximum recommended human dose of 0.3 mg per injection (based on a 60 kg person), assuming complete systemic absorption of trypan blue. Characteristic anomalies included neural tube, cardiovascular, vertebral, tail, and eye defects. Trypan blue also caused an increase in post-implantation mortality and decreased fetal weight. In the monkey, trypan blue caused abortions with single or two daily doses of 50 mg/kg between 20th to 25th days of pregnancy, but no apparent increase in birth defects (approximately 3,200-fold the maximum recommended human dose based on BSA, assuming complete systemic absorption).

8.2 Lactation
Risk Summary
The presence of trypan blue in human milk following intraocular administration of trypan blue has not been evaluated. There are no data available regarding the effects of trypan blue on milk production. Breastfeeding is not expected to result in exposure of the child to trypan blue due to the negligible systemic exposure of trypan blue in humans following injection and subsequent removal of the drug at the completion of surgical procedures.

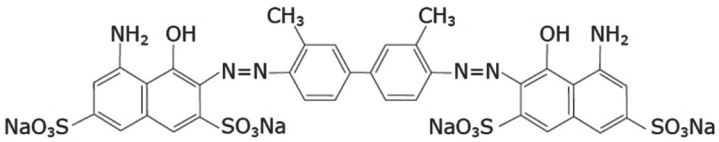
8.4 Pediatric Use
The safety and effectiveness of trypan blue have been established in pediatric patients. Use of trypan blue is supported by evidence from an adequate and well-controlled study in pediatric patients.

8.5 Geriatric Use
No overall differences in safety and effectiveness were observed between elderly and younger patients.

11 DESCRIPTION
VisionBlue® (trypan blue ophthalmic solution) 0.06% is a sterile solution of trypan blue (an acid di-azo group dye) for intraocular ophthalmic use. VisionBlue® 0.06% is a selective tissue staining agent for use as a medical aid in ophthalmic surgery.

Each mL of VisionBlue® 0.06% contains: 0.6 mg trypan blue; 1.9 mg sodium mono-hydrogen orthophosphate (Na2HPO4.2H2O); 0.3 mg sodium di-hydrogen orthophosphate (NaH2PO4.2H2O); 8.2 mg sodium chloride (NaCl); and water for injection. Sodium hydroxide may be used to adjust pH. The pH is 7.3 - 7.6. The osmolality is 257-314 mOsm/kg.

The drug substance trypan blue has the chemical name 3,3'-[(3,3'-dimethyl-4,4'-biphenylylene) bis (azo)] bis(5- amino-4-hydroxy-2,7-naphthalenedisulfonic acid) tetra sodium salt, a molecular weight of 960.8, a molecular formula of C34H24N6Na4O14S4, and has the following chemical structure:



12 CLINICALPHARMACOLOGY

12.1 Mechanism of Action

VisionBlue® 0.06% selectively stains connective tissue structures in the human eye such as the anterior lens capsule of the human crystalline lens.

VisionBlue® 0.06% 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.

13 NONCLINICALTOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Trypan blue is carcinogenic in rats. Wister/Lewis rats developed lymphomas after receiving subcutaneous injections of 1% trypan blue dosed at 50 mg/kg every other week for 52 weeks (total dose approximately 42,000-fold the maximum recommended human dose of 0.3 mg per injection in a 60 kg person based on BSA, assuming complete systemic absorption).

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

16 HOW SUPPLIED/STORAGE AND HANDLING

VisionBlue® 0.06% is is a clear, dark blue ophthalmic solution supplied as follows:
0.5 mL of VisionBlue® 0.06% in a sterile single-patient-use Luer Lok, 2.25 mL glass syringe, grey rubber plunger stopper and tip cap with polypropylene plunger rod in a peel pouch. Ten pouched products are packed in one distribution box.

NDC 68803-612-05 (One 0.5 mL syringe)
NDC 68803-612-10 (Carton of ten 0.5 mL syringes)

Storage: Store between 15ºC to 25ºC (59ºF to 77ºF). Protect from direct sunlight.

17 PATIENT COUNSELING INFORMATION

Advise patients that if a non-hydrated, hydrophilic acrylic intraocular lens (IOL) is inserted into their eye, it may absorb the dye and become stained.

Made in Germany

Distributed in the United States by
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