

VISIONBLUE- trypan blue injection, solution
D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.

HIGHLIGHTS OF PRESCRIBING INFORMATION

VisionBlue® 0.06% Trypan blue Ophthalmic Solution. These highlights do not include all the information needed to use VISIONBLUE® 0.06% safely and effectively. see full prescribing information for VISIONBLUE® 0.06%. VisionBlue® (trypan blue ophthalmic solution) 0.06% Initial U.S. Approval: 2004

----- **INDICATIONS AND USAGE** -----

HIGHLIGHTS OF PRESCRIBING INFORMATION (1)

These highlights do not include all the information needed to use VISIONBLUE® 0.06% safely and effectively. see full prescribing information for VISIONBLUE® 0.06%. VisionBlue® (trypan blue ophthalmic solution) 0.06% Initial U.S. Approval: 2004 (1)

(1)

VisionBlue® 0.06% is an acid di-azo group 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.

----- **DOSAGE FORMS AND STRENGTHS** -----

VisionBlue® (trypan blue ophthalmic solution) 0.06% in a volume of 0.5 mL. (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)

(6)

To report SUSPECTED ADVERSE REACTIONS contact FDA at 1-800-FDA-1088 or

www.fda.gov/medwatch (6)

----- **USE IN SPECIFIC POPULATIONS** -----

Trypan blue should not be given to pregnant women. (7)

Revised: 12/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

VisionBlue 0.06% - Indications & Usage Section

VisionBlue 0.06% - Dosage & Administration Section

VisionBlue 0.06% - Dosage forms & Strengths section

VisionBlue 0.06% - Contraindications section

VisionBlue 0.06% - Warnings and Precautions section

VisionBlue 0.06% - Adverse Reactions section

VisionBlue 0.06% - Use in specific populations section

VisionBlue 0.06% - Pregnancy section

VisionBlue 0.06% - Nursing Mothers section

VisionBlue 0.06% - Pediatric use section

VisionBlue 0.06% - Geriatric use section

VisionBlue 0.06% - Description section

VisionBlue 0.06% - Clinical Pharmacology section

VisionBlue 0.06% - Mechanism of action section

VisionBlue 0.06% - Nonclinical toxicology section

VisionBlue 0.06% - Carcinogenesis & Mutagenesis & Impairment of fertility section

VisionBlue 0.06% - How supplied section

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

VisionBlue 0.06% - Indications & Usage Section

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

VisionBlue 0.06% - Dosage & Administration Section

Cataract surgery.

VisionBlue® 0.06% is packaged in a 2.25 mL syringe 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.

VisionBlue 0.06% - Dosage forms & Strengths section

VisionBlue® 0.06% is supplied in 2.25 mL syringes filled to a volume of 0.5 mL.

VisionBlue 0.06% - Contraindications section

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.

VisionBlue 0.06% - Warnings and Precautions section

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.

VisionBlue 0.06% - Adverse Reactions section

Adverse reactions reported following use of VisionBlue® 0.06% 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.

VisionBlue 0.06% - Use in specific populations section

VisionBlue 0.06% - Pregnancy section

Teratogenic Effects: Pregnancy Category C. 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. These doses are approximately 10,000- and 5,000-fold the maximum recommended human dose of 0.3 mg per injection based in a 60 kg person, assuming that the whole dose is completely absorbed. 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 10,000-fold the maximum recommended human daily dose of 0.3 mg per injection, assuming total absorption). 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.

VisionBlue 0.06% - Nursing Mothers section

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.

VisionBlue 0.06% - Pediatric use section

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.

VisionBlue 0.06% - Geriatric use section

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

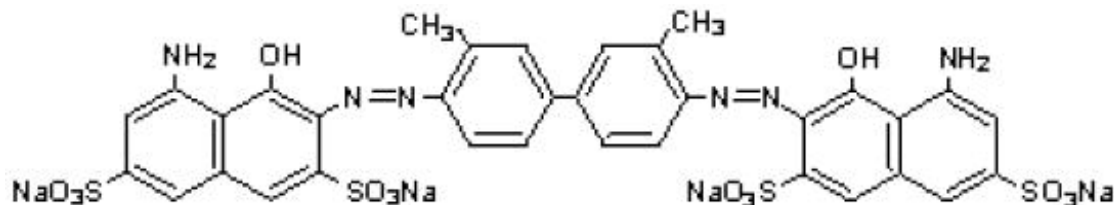
VisionBlue 0.06% - Description section

VisionBlue® (trypan blue ophthalmic solution) 0.06% is a sterile solution of trypan blue (an acid di-azo group dye). 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 ($\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$); 0.3 mg sodium di-hydrogen orthophosphate ($\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$); 8.2 mg sodium chloride (NaCl); and water for injection. 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'-biphenylene) bis (azo)] bis (5-amino-4-hydroxy-2,7-naphthalenedisulfonic acid) tetra sodium salt, a molecular weight of 960.8, a molecular formula of $\text{C}_{34}\text{H}_{24}\text{N}_6\text{Na}_4\text{O}_{14}\text{S}_4$, and has the following chemical structure:



VisionBlue 0.06% - Clinical Pharmacology section

VisionBlue 0.06% - Mechanism of action section

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.

VisionBlue 0.06% - Nonclinical toxicology section

VisionBlue 0.06% - Carcinogenesis & Mutagenesis & Impairment of fertility section

Trypan blue is carcinogenic in rats. Wistar/Lewis rats developed lymphomas after receiving subcutaneous injections of 1% trypan blue dosed at 50 mg/kg every other week for 52 weeks (total does approximately 250,000-fold the maximum recommended human dose of 0.3 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.

VisionBlue 0.06% - How supplied section

VisionBlue® 0.06% is supplied as follows:

0.5 mL of VisionBlue® 0.06% in a sterile single-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 on distribution box.

VisionBlue 0.06% - Storage and Handling section

Store between 15-25°C (59-77°F). Protect from direct sunlight.

VisionBlue 0.06% - Patient counseling information

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

Manufactured by

D.O.R.C. International b.v.

Scheijdelveweg 2

3214 VN Zuidland

The Netherlands

Distributed in the United States by

Dutch Ophthalmic, USA

10 Continental Drive, Bldg 1

Exeter, NH 03833, USA

Phone: 800-75-DUTCH or 603-778-6929

US Patents 6,367,480 and 6,720,314

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VisionBlue 0.06% - Package label.Principal display panel

D642e-4

VISIONBLUE®
SYRINGE
DORC
0.06% Trypan Blue
Ophthalmic Solution

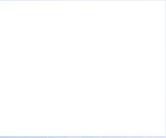
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DORC

DORC

DORC

See package insert for dosing information



Leave syringe in pouch until use. Protect from light, frost and moisture. Store at 15° C to 25° C (59° F to 77° F). Sterile.

Active ingredients: Trypan blue 0.06%.

Excipient ingredients: Water for injection, Sodium chloride, Sodium phosphate dibasic dihydrate, Sodium phosphate monobasic dihydrate

Labeler code no.: 68803-612 **Rx ONLY**

Dutch Ophthalmic Research Center International BV
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Fax: (+31) 181 45 80 90
E-mail: mailto@dorc.nl

VISIONBLUE®
SYRINGE
0.06% Trypan Blue
Ophthalmic Solution

Manufactured by
DORC
Dutch Ophthalmic Research Center
International BV
Scheijdelweg 2
3214 WH Zandveld
The Netherlands

Distributed in the USA by
DUTCH
Ophthalmics, Inc.
Dutch Ophthalmic, USA
10 Continental Drive, Steg 1
Exeter, NH 03833, USA
Phone: 800-75-DUTCH or 603-778-6929

VISIONBLUE®
SYRINGE
0.06% Trypan Blue
Ophthalmic Solution

Staining solution for intracocular use
Solution colorante pour l'utilisation intraoculaire
Solución tñada para uso intracocular

US Patents
6,367,480 and 6,720,314

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DORC

VISIONBLUE®
SYRINGE
0.06% Trypan Blue
Ophthalmic Solution

68803-612

DORC

VisionBlue[®] 0.06% Trypan Blue Ophthalmic Solution

Single use only 0.5 mL Syringe

STERILE  **Rx Only** **LOT**

See package insert for dosing information. Protect from direct sunlight.

Manufactured by: D.O.R.C. International b.v.
 Scheijdelweg 2
 3214 VN Zuidland, The Netherlands

Distributed in US by: Dutch Ophthalmic, USA, Exeter, NH 03833
 (800) 753-8824 or (603) 778-6929

VisionBlue[®] 0.06% Trypan Blue Ophthalmic Solution

LOT 00000 **Expiration Date** 0000-00

Dutch Ophthalmic, USA, Exeter, NH 03833
 (800) 753-8824 or (603) 778-6929

D642b-4

DORC **STERILE**  D642b-4

VisionBlue[®] 0.06% Trypan Blue Ophthalmic Solution

10 Luer Lok 2.25mL Syringes of 0.5mL

Store at 15° to 25°C (59°F to 77°F). Leave in pouch until use. Rx Only



68803-612

Protect from direct sunlight. Single use only.

LOT 00000

Expiration Date 0000-00

Manufactured by: D.O.R.C. International b.v.
 Scheijdelweg 2; 3214 VN Zuidland – The Netherlands

Distributed in US by: Dutch Ophthalmic, USA
 Exeter, NH 03833
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DORC **STERILE**  D642g-4

VisionBlue[®] 0.06% Trypan Blue Ophthalmic Solution

1 Luer Lok 2.25mL Syringe of 0.5mL

Store at 15° to 25°C (59°F to 77°F). Leave in pouch until use. Rx Only



68803-612

Protect from direct sunlight. Single use only.

LOT 00000

Expiration Date 0000-00

Manufactured by: D.O.R.C. International b.v.
 Scheijdelweg 2; 3214 VN Zuidland – The Netherlands

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 Exeter, NH 03833
 (800) 753-8824 or (603) 778-6929

Release:

D642f-4

MADE IN
GERMANY

DORC

VisionBlue[®] 0.06% syringe 0.5mL
Trypan Blue Ophthalmic Solution

VBL-10S.USA



VBL-10S.USA

Shipper: 000

LOT

00000



00000

Quantity: 12



0000-00

Manufactured by:

D.O.R.C International b.v.
Scheijdelveweg 2; 3214 VN
Zuidland - The Netherlands

Distributed in US by:

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Exeter, NH 03833
(800) 753-8824 or (603) 778-6929

VISIONBLUE

trypan blue injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68803-612
Route of Administration	OPHTHALMIC, INTRAOCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRYPAN BLUE (UNII: I2ZW03LS3M) (TRYPAN BLUE FREE ACID - UNII: 768N7QO4KH)	TRYPAN BLUE	0.3 mg in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	0.15 mg in 0.5 mL
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	0.85 mg in 0.5 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	4.1 mg in 0.5 mL
WATER (UNII: 059QF0KO0R)	0.5 mL in 0.5 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68803-612-10	10 in 1 CARTON	12/16/2004	
1		1 in 1 POUCH		
1		0.5 mL in 1 SYRINGE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021670	12/16/2004	

Labeler - D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. (407522184)

Registrant - D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. (407522184)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmpur GmbH		340805167	manufacture(68803-612)

Revised: 10/2023

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.