

TISSUEBLUE- brilliant blue g injection, solution
D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.

HIGHLIGHTS OF PRESCRIBING INFORMATION

TissueBlue: These highlights do not include all the information needed to use TISSUEBLUE 0.025% safely and effectively. See full prescribing information for TISSUEBLUE 0.025%. TISSUEBLUE (Brilliant Blue G Ophthalmic Solution) 0.025%, for intraocular ophthalmic use Initial U.S. Approval: 2019

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

TissueBlue 0.025% is a disclosing agent indicated to selectively stain the internal limiting membrane (ILM). (1)

----- **DOSAGE AND ADMINISTRATION** -----

- Inject TissueBlue 0.025% directly in a Balanced Salt Solution (BSS)-filled vitreous cavity.
- Excess TissueBlue should be removed from the vitreous cavity.

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

TissueBlue (Brilliant Blue G Ophthalmic Solution) 0.025% is supplied in 2.25 mL syringes filled to a volume of 0.5 mL. (3)

----- **CONTRAINDICATIONS** -----

None (4)

----- **WARNINGS AND PRECAUTIONS** -----

Excessive staining: Excess TissueBlue 0.025% should be removed from the eye immediately after staining.

Use of the syringe: Make sure the plunger moves smoothly before injecting the solution. (5)

----- **ADVERSE REACTIONS** -----

Adverse reactions that have been reported in procedures that included the use of TissueBlue 0.025% have often been associated with the surgical procedure. The complications include retinal (retinal break, tear, hemorrhage, and detachment and cataracts). (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 (6)

Revised: 5/2025

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

FULL PRESCRIBING INFORMATION

TissueBlue 0.025% - Indications & Usage Section

TissueBlue 0.025% is indicated to selectively stain the internal limiting membrane (ILM).

TissueBlue 0.025% - Dosage & Administration Section

TissueBlue 0.025% is carefully injected into the Balanced Salt Solution (BSS)-filled vitreous cavity using a blunt cannula attached to the pre-filled syringe, without allowing the cannula to contact the retina or allowing TissueBlue to get under the retina. Sufficient staining is expected within a few seconds. Following staining, all excess dye should be removed from the vitreous cavity.

TissueBlue 0.025% - Dosage forms & Strengths section

TissueBlue (Brilliant Blue G Ophthalmic Solution) 0.025% is a clear, bright blue, single-dose ophthalmic solution supplied in 2.25 mL syringes pre-filled to a volume of 0.5 mL.

TissueBlue 0.025% - Contraindications section

None

TissueBlue 0.025% - Warnings and Precautions section

Excessive Staining

Excess TissueBlue 0.025% should be removed from the eye immediately after staining.

Use of the Syringe

Make sure the plunger moves smoothly before injecting the solution. Do not use the product if the plunger does not move smoothly to prime the cannula.

TissueBlue 0.025% - Adverse Reactions section

Adverse reactions that have been reported in procedures that included the use of Brilliant Blue G Ophthalmic Solution have often been associated with the surgical procedure. These complications include retinal (retinal break, tear, hemorrhage, and detachment) and cataracts.

TissueBlue 0.025% - Use in specific populations section

TissueBlue 0.025% - Pregnancy section

Risk Summary

There are no available data on the use of TissueBlue 0.025% in pregnant women to inform a drug associated risk. Systemic absorption of TissueBlue 0.025% in humans is expected to be negligible following intravitreal injection and subsequent removal of the drug at the completion of surgical procedures. Due to the negligible systemic exposure, it is not expected that maternal use of TissueBlue 0.025% will result in fetal exposure to the drug.

Adequate animal reproduction studies were not conducted with TissueBlue 0.025%.

TissueBlue 0.025% - Lactation section

Risk Summary

No data are available regarding the presence of Brilliant Blue G in human milk after intraocular administration of TissueBlue 0.025%, or the effects on the breastfed infant or the effects on milk production. However, breastfeeding is not expected to result in exposure of the child to Brilliant Blue G due to the expected negligible systemic exposure of BBG in humans following intravitreal injection and subsequent removal of the drug at the completion of surgical procedures.

TissueBlue 0.025% - Pediatric use section

The safety and effectiveness of TissueBlue 0.025% in pediatric patients has not been established.

TissueBlue 0.025% - Geriatric use section

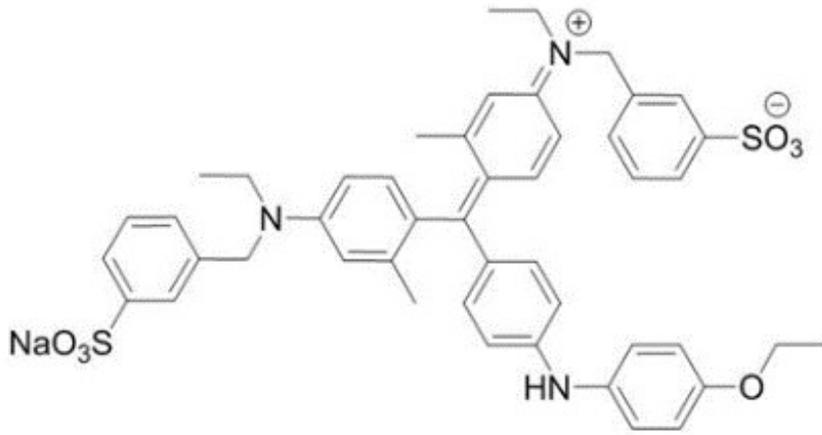
No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

TissueBlue 0.025% - Description section

TissueBlue (Brilliant Blue G Ophthalmic Solution) 0.025% is a sterile solution of BBG (a dye) for intraocular ophthalmic use. Each mL of TissueBlue 0.025% contains BBG 0.25 mg, polyethylene glycol and buffered sodium chloride solution (sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, water for injection). Phosphoric acid and/or sodium hydroxide may also be used for pH adjustment. The pH range of TissueBlue 0.025% Solution is between 7.3 and 7.6.

The drug substance BBG has the chemical name Brilliant Blue G, a molecular weight of 854.02 and has the following chemical structure:

Molecular formula: $C_{47}H_{48}N_3NaO_7S_2$



TissueBlue 0.025% - Clinical Pharmacology section

TissueBlue 0.025% - Mechanism of action section

Brilliant Blue G has been shown to selectively stain the ILM, but not the epiretinal membrane nor the retina, making it easier to visualize the membrane for removal, although the exact mechanism of this selectivity has not been elucidated.

TissueBlue 0.025% - Nonclinical toxicology section

TissueBlue 0.025% - Nonclinical toxicology section

Studies to evaluate the potential for carcinogenicity or impairment of fertility of TissueBlue 0.025% have not been conducted.

Brilliant Blue G was not mutagenic in the Ames assay, the in vitro mouse lymphoma assay, or the in vivo rat micronucleus assay.

TissueBlue 0.025% - How supplied section

TissueBlue (Brilliant Blue G Ophthalmic Solution), 0.025% is supplied as 0.5 mL of Brilliant Blue G Ophthalmic Solution, 0.025% in a sterile, single-dose Luer Lok, 2.25 mL glass syringe, with a grey rubber plunger stopper and tip cap with polypropylene plunger rod in a pre-formed polypropylene blister pouch sealed with a Tyvek® lid.

NDC 68803-722-05 (One 0.5 mL syringe)

NDC 68803-722-25 (Carton of five 0.5 mL syringes)

TissueBlue 0.025% - Storage and Handling section

TissueBlue 0.025% should be stored at 15°C to 25°C (59°F to 77°F). Protect from light, frost and moisture.

Distributed by:

Dutch Ophthalmic, USA
10 Continental Drive, Bldg 1
Exeter, NH 03833, USA
Phone: 800-75-DUTCH or 603-778-6929

Made in Germany

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Package Label - 0.5 mL

TissueBlue

(Brilliant Blue G Ophthalmic Solution) 0.025%

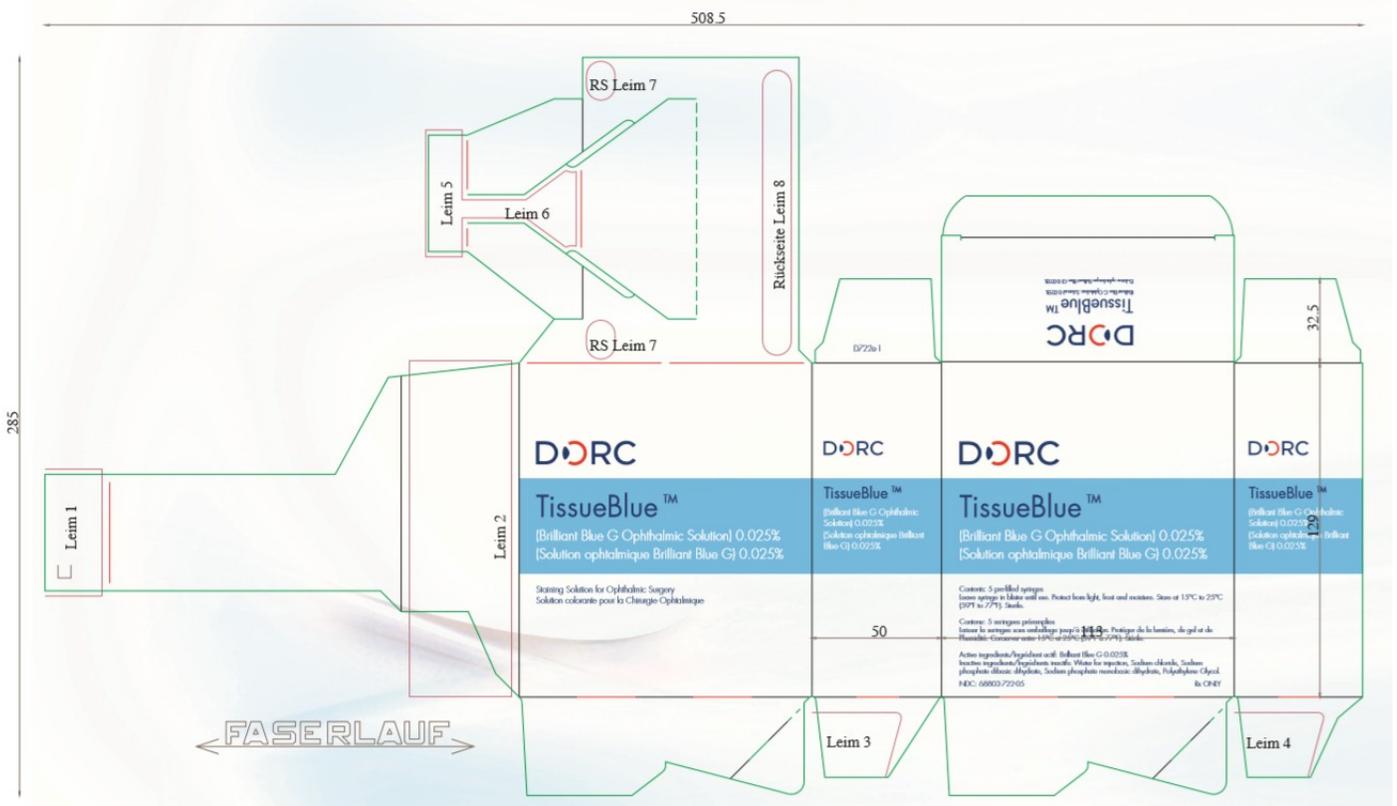
Staining Solution for Ophthalmic Surgery

Protect from light, frost and moisture. Store at 15°C to 25°C (59°F to 77°F). Sterile.

Active ingredients: Brilliant Blue G 0.025% Inactive ingredients: Water for injection, Sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, polyethylene glycol, phosphoric acid and/or sodium hydroxide may also be used for pH adjustment.

NDC 68803-722-05 (One 0.5 mL syringe)

NDC 68803-722-25 (Carton of five 0.5 mL syringes)



TISSUEBLUE

brilliant blue g injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68803-722
Route of Administration	INTRAOCULAR, OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRILLIANT BLUE G (UNII: M1ZRX790SI) (BRILLIANT BLUE G - UNII:M1ZRX790SI)	BRILLIANT BLUE G	0.0125 mg in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8.2 mg in 0.5 mL
SODIUM PHOSPHATE, DIBASIC, DODECAHYDRATE (UNII: E1W4N241FO)	3.1 mg in 0.5 mL
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	0.3 mg in 0.5 mL
WATER (UNII: 059QF0KO0R)	4743 g in 0.5 mL
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	2 mg in 0.5 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68803-722-05	10 in 1 CARTON	12/31/2019	
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	NDA209569	12/31/2019	

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(68803-722)