

## TWIN

0.18% TRYPAN BLUE + 0.03% BLULIFE

6 X 0.7 ML PREFILLED SYRINGES

## TISSUE STAINING

Dveji dažai (trypan blue ir blulife), svorį suteikianti medžiaga (thickening agent)	<b>TWIN</b>
<b>Ingredients</b>	<ul style="list-style-type: none"> <li>▶ trypan blue</li> <li>▶ blulife (<math>C_{48}H_{50}N_3NaO_7S</math>)</li> <li>▶ thickening agent</li> <li>▶ sodium chloride</li> <li>▶ sodium phosphate monobasic</li> <li>▶ sodium phosphate dibasic</li> <li>▶ water for injectables</li> </ul>
<b>Dye concentration</b>	0.162 - 0.198 %w/V trypan blue 0.027 - 0.033 %w/V blulife
<b>Hydrogenionic activity (pH)</b>	7.00 - 7.40 pH units
<b>Osmolality</b>	335 - 360 mOsm/kg
<b>Osmolarity</b>	340 - 365 mOsm/L
<b>Density</b>	1.015 - 1.018 g/ml
<b>Bacterial Endotoxins</b>	< 0.5 EU/ml
Atitinka ISO 10993 (bioatitikties) standartą (naujausią 5 versiją)	Non-cytotoxic according to ISO 10993-5, direct contact test performed on two cell lines: - retinal pigment epithelial cells (ARPE-19) - mouse fibroblasts cells (BALB 3T3 clone A31)
<b>Cytotoxicity Test</b>	
<b>Form</b>	sterile liquid Sterilus skystis
<b>Volume</b>	≥ 0.7 ml
<b>Packaging</b>	syringe Švirkšte
<b>Sterilization</b>	moist heat according to EN 556-1 and EN ISO 17665-1
<b>Storage temperature</b>	+15°C / +32°C
<b>Expiry date</b>	36 months Galioja 36 mėn. (3 metus)
Laikinam tinklainės membraną ir vidinės skiriančiosios membranos (ILM) laikinam dažymui operacijos metu	reversible staining of the retinal membranes and the inner limiting membrane (ILM) during ophthalmic surgery
<b>Intended use</b>	
<b>Class</b>	medical device
<b>GMDN code</b>	P 45180
<b>CND code</b>	Q 02030201
<b>MD registration number</b>	1331847/R
<b>Medical device class</b>	Ila
<b>CE mark</b>	CE 0477

TWIN is 0.18% trypan blue + 0.03% blulife ( $C_{48}H_{50}N_3NaO_7S$ ) in physiological solution, packaged in prefilled syringes of 0.7 ml each, for reversible staining of the retinal membranes and the inner limiting membrane (ILM). The product warrants a prompt and effective tissue staining, without any risks for the patient. It contains a thickening agent that improves the contact between the dyes and the tissues, thus allowing a clear visualization of the retinal membranes and the inner limiting membrane. In addition, it simplifies the surgery, making superfluous the fluid/air exchange performed before the dye injection, in order not to dilute it.

Ref.: RMB 004-00

## Contents:

- ▶ 6 TWIN prefilled syringes, 0.7 ml
- ▶ 6 pistons
- ▶ 1 package insert
- ▶ 12 labels for product traceability

GS1-128 barcode

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