

## TWIN

0.18% TRYPAN BLUE + 0.03% BLULIFE

6 X 0.7 ML PREFILLED SYRINGES

## TISSUE STAINING

	TWIN
<b>Ingredienti</b>	<ul style="list-style-type: none"> <li>▶ trypan blue</li> <li>▶ blulife (C<sub>48</sub>H<sub>50</sub>N<sub>3</sub>NaO<sub>7</sub>S)</li> <li>▶ thickening agent</li> <li>▶ sodium chloride</li> <li>▶ sodium phosphate monobasic</li> <li>▶ sodium phosphate bibasic</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>	245 - 360 mOsm/kg
<b>Density</b>	1.015 - 1.018 g/ml
<b>Bacterial Endotoxins</b>	< 0.5 EU/ml
<b>Cytotoxicity Test</b>	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>Form</b>	sterile liquid
<b>Volume</b>	≥ 0.7 ml
<b>Packaging</b>	syringe
<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
<b>Intended use</b>	reversible staining of the retinal membranes and the inner limiting membrane (ILM) during ophthalmic surgery
<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<sub>48</sub>H<sub>50</sub>N<sub>3</sub>NaO<sub>7</sub>S) 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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