

TWIN

0.18% TRYPAN BLUE + 0.03% BLULIFE

6 X 0.7 ML PREFILLED SYRINGES

TISSUE STAINING

	TWIN
Ingredients	<ul style="list-style-type: none"> ▶ trypan blue ▶ blulife (C₄₈H₅₀N₃NaO₇S) ▶ thickening agent ▶ sodium chloride ▶ sodium phosphate monobasic ▶ sodium phosphate bibasic ▶ water for injectables
Dye concentration	0.162 - 0.198 %w/V trypan blue 0.027 - 0.033 %w/V blulife
Hydrogenionic activity (pH)	7.00 - 7.40 pH units
Osmolality	335 - 360 mOsm/kg
Osmolarity	340 - 365 mOsm/L
Density	1.015 - 1.018 g/ml
Bacterial Endotoxins	< 0.5 EU/ml
Cytotoxicity Test	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)
Form	sterile liquid
Volume	≥ 0.7 ml
Packaging	syringe
Sterilization	moist heat according to EN 556-1 and EN ISO 17665-1
Storage temperature	+15°C / +32°C
Expiry date	36 months
Intended use	reversible staining of the retinal membranes and the inner limiting membrane (ILM) during ophthalmic surgery
Class	medical device
GMDN code	P 45180
CND code	Q 02030201
MD registration number	1331847/R
Medical device class	Ila
CE mark	CE 0477

TWIN is 0.18% trypan blue + 0.03% blulife (C₄₈H₅₀N₃NaO₇S) 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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