

MONOBLUE DUAL View

General Features

MONOBLUE DUAL View is an ultra-purified Trypan blue and DDG solution presented in a single dose syringe with 0.5 ml of 0,09% Trypan blue 0,025% DDG.

MONOBLUE DUAL View is indicated for the staining of the epiretinal membrane and the internal limiting membrane (ERM/ILM).



Product Description

Composition	MONOBLUE DUAL View: DDG 0.025% (m/v), Trypan blue 0.09% (m/v), Diglycerol 2.6% (m/v), Phosphate buffer qsp 0.5 mL MONOBLUE DUAL View contains no natural latex or preservatives.
Density	1.008 - 1.010 mg/mL
Extractable Volume	≥ 0.5 mL
Source	Chemical synthesis + high purification
Osmolality	350 – 400 mOsm/kg (H2O)
рН	7.0 – 7.5
BVI product code	609

Product Information

Minimally Invasive Staining Solution	Name	General Device Description	Qty/Bx	SKU#
● BVI MONOBLUE DUAL	MONOBLUE DUAL View	GTIN 1 376013064 054 8 GMDN 45 180 – "Ophthalmic surgical dye", ophthalmology	5	609

Product Information

Packaging	General Device Desciption		
5 pre-filled glass syringes per box, individually packed in a paper peel pouch with a female/female connector 1 multilanguage Instructions for Use Supplied with 5x1mL tuberculin syringes in a peelable pouch.	Name MONOBLUE DUAL View Reference Code CT 230 GTIN 1 376013064 054 8 GMDN 45 180 – "Ophthalmic surgical dye"		
Manufacturer	Product Class		
Acadophta 11 rue Antoine Ricord 31100 Toulouse - France	Class IIa sterile, single use		
OR Requirements	Shelf Life		
Sterile medical devices intended for use as an aid in the vitrectomy procedure during vitreoretinal surgery adults: DUAL View is indicated for the staining of the epiretinal membrane and the internal limiting membrane (ERM/ILM). It is intended for ophtalmologists experienced in vitrectomy surgical procedures	Two (2) years from manufacturing date		
Certification Information	Absence of		
EC Certification: 37858 CE mark: CE 0459 FDA approval: NA Notified Body: GMED	Natural latex or preservatives		
CE mark: CE 0459 FDA approval: NA Notified Body: GMED ISO: NF EN ISO 13485:2016			
CE mark: CE 0459 FDA approval: NA Notified Body: GMED	Packaging Material Primary: Type I Glass Secondary: Paper peel pouch and carton box		
CE mark: CE 0459 FDA approval: NA Notified Body: GMED ISO: NF EN ISO 13485:2016 Sterilisation	Primary: Type I Glass		

