

GOT C₂F₆ MULTI

PURE HEXAFLUOROETHANE FOR INTRAOCULAR TAMPONADE

OPHTHALMIC GAS

	Gas cylinder	Set for gas withdrawal, filtration and injection
Ingredient	pure hexafluoroethane	plastic
Purity	> 99%	not applicable
Form	non-sterile gas	sterile solid
Amount	75 ml	1 set
Packaging	aluminium cylinder with multilayer bag	polypropylene blister tray
Sterilization	sterile cylinder by ethylene oxide (according to EN ISO 11135-1)	ethylene oxide (according to EN ISO 11135-1)
Ethylene oxide residuals	< 1.25 µg/dose according to EN ISO 16672	< 4 mg/device according to EN ISO 10993-7
Ethylene chlorohydrin residuals	< 5.00 µg/dose in accordance with EN ISO 16672	< 9 mg/device according to EN ISO 10993-7
Storage temperature	do not expose to temperatures above 50°C/112°F	
Expiry date	24 months	
Intended use	intraocular tamponade during vitreoretinal surgery	withdrawal, filtration and intraocular injection of ophthalmic gas
Tamponade time	30 - 40 days	not applicable
Non-expansile concentration	16%	not applicable
Non-expansile volume	8 ml of gas + 42 ml of air	not applicable
Class	medical device	
GMDN code	45125	
CND code	Q 02030101	
MD registration number	3731/R	
Medical device class	IIb	
CE mark	CE 0477	

GOT Multi C₂F₆ is pure hexafluoroethane, 75ml, packaged in aluminium cylinder, intended for long-term replacement of the vitreous humour extracted during vitreoretinal surgery. Product can be used until cylinder content is consumed. Special 75 ml cylinder with multi-layer bag resists pressure variations, ensuring shipping by air without any problems or limitations. Package includes an injection set made of a pre-assembled polypropylene 60 ml-syringe to a 0.2 µm sterilizing filter, a connector and a 30G needle.

Ref.: GOT 008-00

Contents:

- ▶ 1 cylinder of 75 ml pure gas
- ▶ 1 injection set made of
 - 1 60 ml-polypropylene syringe,
 - 1 0.2 µm sterilizing filter,
 - 1 connector, and 1 30G needle
- ▶ 1 patient wristband with warnings
- ▶ 12 labels for product traceability
- ▶ 1 package insert

GS1-128 barcode

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