



### Product Description:

OptiLube is a sterile, transparent, water-soluble lubricating jelly with a pH range of 5.0 – 7.0.

### Intended Use:

OptiLube is a medical device that is a water-soluble, sterile lubricating jelly intended for the smooth insertion of medical devices, and examinations, reducing the risk of trauma during procedures, including:

- Insertion of catheters • Endoscopy • Gynaecological examinations
- Rectal examinations • Cystoscopy

### Storage:

- Keep dry
- Keep out of direct sunlight
- Do not use after expiry date
- Store between 5°C and 40°C

### Duration of use:

<b>Shelf Life</b>	5 years
<b>Lifetime</b>	Single use
<b>Expiry</b>	Do not use after expiry date

### Product Range:

Product Code	Volume	Format	Lid Type
1123	2.7g	Sachet	N/A
1123B	2.7g	Sachet Bulk	N/A
1120	5g	Sachet	N/A
1119	20g	Sachet – Double wrapped	N/A
1119S	20g	Sachet – Single Wrapped	N/A
1124	5g	Tube	Screw
1114	10g	Tube	Flip
1121	42g	Tube	Flip
1121UK	42g	Tube	Screw
1122	82g	Tube	Flip
1122UK	82g	Tube	Screw
1127	113g	Tube	Flip

### Product Materials:

Component / Part	Material
Lubricating Jelly	Purified Water, PEG, Glycerine, Sodium Hydroxide, Carbomer, 4-Hydroxybenzoic acid esters
Sachet	Laminated Foil
Tube (1114, 1121UK, 1122UK)	Low-density polyethylene [LDPE]
Tube (1121, 1122, 1124, 1127)	Aluminium plastic composite [Polyethylene + aluminium + polyethylene]
Tube Lid [All variants]	Polypropylene
Inner Box	Cardboard
Outer Box	Double walled corrugated cardboard



### Standards:

<b>CE marked</b>	Yes
<b>Device classification</b>	Class IIa under UK MDR Class IIb under MDR
<b>Quality management</b>	EN ISO 13485:2016

### Sterilisation:























<b>Sterile</b>	Yes
<b>Sterilisation process</b>	Gamma Irradiation

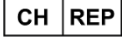





Packaging specifications:

Product Ref	Primary Packaging Sachet	Secondary Packaging Inner Box		Tertiary Packaging Outer Box		
	Dimensions [mm]	Quantity [Units]	Dimensions [mm]	Quantity [Inner Boxes]	Quantity [Units]	Dimensions [mm]
1123	80 x 35	144	165 x 120 x 72	10	1440	390 x 260 x 185
1123B	80 x 35	720	250 x 165 x 180	2	1440	380 x 250 x 180
1120	85 x 40	150	175 x 140 x 82	10	1500	440 x 300 x 195
1119	65 x 130	20	180 x 92 x 182	10	200	490 x 380 x 200
1119S	65 x 130	20	180 x 70 x 140	10	200	380 x 380 x 160

Product Ref	Primary Packaging Tube		Secondary Packaging Tube Box		Tertiary Packaging Inner Box		Outer Box		
	Tube Length [mm]	Tube Diameter [mm]	Quantity [Units]	Dimensions [mm]	Quantity [Units]	Dimensions [mm]	Quantity [Inner Boxes]	Quantity [Units]	Dimensions [mm]
1124	55	16	N/A	N/A	48	115 x 85 x 75	10	480	450 x 170 x 130
1114	65	25	N/A	N/A	30	170 x 140 x 85	10	300	720 x 360 x 105
1121	115	28	1	35 x 35 x 140	12	145 x 145 x 110	6	72	350 x 310 x 165
1121UK	115	30	N/A	N/A	12	135 x 145 x 75	12	144	415 x 300 x 155
1122	125	35	1	43 x 43 x 152	12	175 x 160 x 135	6	72	510 x 370 x 155
1122UK	125	35	N/A	N/A	12	160 x 155 x 80	12	144	500 x 330 x 180
1127	155	35	1	43 x 43 x 180	12	185 x 175 x 135	6	72	550 x 390 x 155

Symbols:

Symbol	Description	Symbol	Description
	Legal manufacturer		Importer - Indicates the entity importing the medical device into the European market
	Authorised Representative in the European Community		Medical Device
	Indicates that the product is in compliance with European legislation for medical devices		Indicates that the product is in compliance with UK legislation for medical devices
	UDI - Indicates Unique Device Information		Use-by Date YYYY-MM-DD
	Date of Manufacture – China		Catalogue Number
	Batch Code		Caution
	Country of manufacture		Consult Instructions for Use
	Keep dry		Keep Away from Sunlight
	Latex Free		Do not Use if Damaged and Consult IFU
	Single use on a single patient		Do not resterilise
	Sterile – Gamma Radiation		Demonstrates that the packaging layer is capable of being recycled

Symbol	Description	Symbol	Description
	Swiss Authorised Representative		Left hand side confirms the plastic type (resin code 4/LDPE) and on the right side the recycling instructions: Top is the layer being referred to and bottom is recycling instruction
	Single Sterile Barrier System		Left hand side confirms the plastic type (resin code 5/PP) and on the right side the recycling instructions: Top is the layer being referred to and bottom is recycling instruction
	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed		Indicates Sachet is Non-recyclable

Manufacturers Information:

Product	Legal Manufacturer	Address
OptiLube Sachets and Tubes	Optimum Medical Solutions Limited	Tennant Hall Blenheim Grove, Leeds, United Kingdom, LS2 9ET