



### Product Specification - OptiLube Sachets (2.7g, 5g, 20g)

CPS – 2017 - 001

#### 1. General Information



1.1 General description: Sterile lubricating gel

1.2 Intended use: OptiLube gel is used to aid the smooth insertion of medical devices in procedures including insertion of catheters, endoscopy, gynaecological examination, rectal examinations and cystoscopy

1.3 Product code:            1119S            1119DW            1120            1123

1.4 Formats:                            20g            20g            5g            2.7g

1.5 Lifetime of device: Single use

*Document released via DCR- 302 on 12 Jun 2018  
Issue: 5*



## 2. Materials

### 2.1 Lubricating gel

Glycerine  
 Polyethylene glycol  
 Methyl paraben  
 Propyl paraben  
 Sodium hydroxide (pH regulator)  
 Purified water  
 Carbomer

### 2.1 Sachet

	Sachet material	Sachet dimensions (mm)	Pouch (cm)	Weight per pcs (g)	Seal strength (/ 15mm)	Sealing width (mm)
<b>1123 – 2.7g</b>	PE + aluminium + Paper	35 x 80	NA	3.1 – 3.7	≥15N	Sides: 5 – 7 Top: 3 – 5 Bottom: 5 – 7
<b>1120 - 5g</b>	PE + aluminium + Paper	40 x 85	NA	5.5 – 6.1	≥15N	Sides / bottom: 5 – 7 Top: 4 – 6
<b>1119s - 20g</b>	Aluminium + PE + PET	65 x 120	NA	23.2 – 23.6	≥12N	Sides / bottom: 4 – 6 Top: 7 – 9
<b>1119 - 20g Double Wrapped</b>	Aluminium + PE + PET	65 x 120	9.5 X 18	23.2 – 23.6	≥12N	Sides / bottom: 4 – 6 Top: 7 – 9

*Document released via DCR- 302 on 12 Jun 2018*  
*Issue: 5*



### 3. Packaging

	Inner box (cm)  (Printed white card)	Carton (cm)  (Brown corrugated double wallboard, B flute, 3mm)	Carton weight (g/m <sup>2</sup> )	Pcs per Inner box	Boxes per carton
<b>1123 – 2.7g</b>	16.5 x 12.0 x 7.2	39 x 26 x 18.5	790 – 850	144	10
<b>1120 - 5g</b>	17.5 x 14 x 8.2	44 x 30 x 19.5	790 – 850	150	10
<b>1119s - 20g</b>	18 x 9.2 x 18.2	49 x 38 x 20	790 – 850	20	10
<b>1119DW - 20g</b>	18 x 9.2 x 18.2	49 x 38 x 20	790 – 850	20	10

### 4. Physical properties

- 4.1 Visual Appearance: Colourless to pale, transparent gel
- 4.2 Density: 1.0 +/- 0.1 g/mL
- 4.3 Viscosity: 13000 - 18000cP
- 4.4 pH: 5.0 – 7.0
- 4.5 Solubility in water: Soluble
- 4.6 Sterilisation: Gamma irradiation (25.3 – 50.6 kGy)

### 5. Storage conditions

- 5.1 Store away from direct sunlight
- 5.2 Keep dry
- 5.3 Keep at ambient temperatures
- 5.4 Shelf Life: 5 years

*Document released via DCR- 302 on 12 Jun 2018  
Issue: 5*

