

Product Specifications

Brand : Klinion®

Product : Kliniderm® Super Fiber + Antimicrobial Polymer Technology (APT™)

Product description

Kliniderm Super Fiber + APT™ are 200 gsm fibers, they are soft and conformable non-woven dressings made from sodium, carboxymethylcellulose (CMC) fibers and strengthening cellulose fibers with antimicrobial polymer, quaternary polyethyleneimine (QPEI).

The QPEI polymer when incorporated into the wound dressing, and in contact with wound exudate, prevents bacterial colonization in the dressing due to its antimicrobial activity. The absorption of exudate into the dressing forms a gel that assists in maintaining a moist wound environment, supports autolytic debridement and improves the wound edge and surrounding skin from maceration. Through the gel formation the structure of the dressing remains intact. When dry, Kliniderm Super Fiber + APT™ can easily be cut to the size of the wound. Even when the dressing is moist, as gelled fiber, its structure remains intact. The high vertical absorption of exudate into the fiber dressing improve the wound environment and the wound edge. The product can also be used under compression. Kliniderm Super Fiber + APT™ are provided in different sizes, in rope or pad, with a basic weight of 200gsm and composed of 80% w/w CMC and 20% Tencel/Lyocell fibers.



Intended use

The product is for single use only. Under the supervision of a healthcare professional, Kliniderm Super Fiber + APT™ wound dressings may be used for the management of:

- Wounds with moderate to heavy exudate
- Acute or chronic wounds
- Leg ulcers, pressure ulcers (stage ii to iv) and diabetic ulcers
- Surgical wounds (e.g. post-operative, wounds left to heal by secondary intent and donor sites)
- Traumatic wounds (e.g. abrasions and lacerations)
- Exuding oncology wounds
- Superficial or cavity wounds
- Improves the wound edge and the surrounding skin from maceration¹.

¹ The properties mentioned above refer to the current in vitro data.

Classification

Class IIb under Regulation (EU) 2017/745 Medical Device Regulation (MDR).

Product Specifications

Packaging & Product Reference

Product Reference	Description	Size (*)	Piece(s)	Inner Carton (pcs)	Outer Carton (pcs)
40511813	KLINION® Kliniderm® Super Fiber + APT™ 5x5cm	5x5cm	1	10	200
40511814	KLINION® Kliniderm® Super Fiber + APT™ 10x10cm	10x10cm	1	10	100
40511815	KLINION® Kliniderm® Super Fiber + APT™ 15x15cm	15x15cm	1	5	50
40511816	KLINION® Kliniderm® Super Fiber + APT™ 2x45cm	2x45cm	1	5	100

Product Reference	Description	Size (*)	EAN code peel pouch	EAN Inner Carton	EAN Outer Carton
40511813	KLINION® Kliniderm® Super Fiber + APT™ 5x5cm	5x5cm	7640328070458	7640328070373	7640328070410
40511814	KLINION® Kliniderm® Super Fiber + APT™ 10x10cm	10x10cm	7640328070342	7640328070380	7640328070427
40511815	KLINION® Kliniderm® Super Fiber + APT™ 15x15cm	15x15cm	7640328070359	7640328070397	7640328070434
40511816	KLINION® Kliniderm® Super Fiber + APT™ 2x45cm	2x45cm	7640328070366	7640328070403	7640328070441

*Sizes are approximate

Product Reference	Medeco article #	Description	Dimension peel pouch	Dimension inner carton	Dimension outer carton
40511813	3074333	KLINION® Kliniderm® Super Fiber + APT™ 5x5cm	90x142 mm	97x40x147 mm	406x205x152 mm
40511814	3074370	KLINION® Kliniderm® Super Fiber + APT™ 10x10cm	144x184 mm	146x40x193 mm	298x199x206 mm
40511815	3074371	KLINION® Kliniderm® Super Fiber + APT™ 15x15cm	210x240 mm	213x26x245 mm	215x265x250 mm
40511816	3074372	KLINION® Kliniderm® Super Fiber + APT™ 2x45cm	95x260 mm	97x40x263 mm	297x269x280 mm

*Sizes are approximate

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Product Reference	Medeco article #	Description	Gross weight peel pouch	Gross weight inner carton	Gross weight outer carton
40511813	3074333	KLINION® Kliniderm® Super Fiber + APT™ 5x5cm	2.43 grams	48.9 grams	1150 grams
40511814	3074370	KLINION® Kliniderm® Super Fiber + APT™ 10x10cm	6 grams	95 grams	1100 grams
40511815	3074371	KLINION® Kliniderm® Super Fiber + APT™ 15x15cm	12.1 grams	108.5 grams	1230 grams
40511816	3074372	KLINION® Kliniderm® Super Fiber + APT™ 2x45cm	5.5 grams	61.3 grams	1460 grams

*Sizes are approximate

Features

- Improve wound management by reducing bacterial colonization within the dressing.
- Improve wound healing by providing a moist wound environment and supporting autolytic debridement.
- Reduction of wound complications such as maceration and deterioration of wound edges/peri-wound skin.
- Removable in one piece
- Non-adherent
- Up to 7 days wear time
- Designed for antimicrobial functionality while reducing the risk of antimicrobial resistance

Precautions

- Kliniderm Super Fiber + APTTM is not intended to be used on wounds with severe bleeding, inside internal body cavities or closed wounds.
- Kliniderm Super Fiber + APTTM is for single-use only and should not be re-used. Reuse may lead to increased risk of infection and cross-contamination.
- The dressing shall not be used in infants, children, or vulnerable populations (e.g., pregnant or breastfeeding women) due to a lack of clinical evidence.
- Do not re-sterilize
- Do not use if the primary package is open or damage prior use. Dispose the device according to local regulations.

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- Keep out of reach of children.
- Don't use the product after expiry date

Specifications

Wet Tensile Strength (N/cm)	Machine Direction (MD)	≥0.6
	Cross Direction (XD)	≥4.0
Fabric Absorbency (g/100cm2)	≥26	

Presence of specific components

Component	Present
Latex	No
Phthalates	No
Substances of animal origin	No
Substances of human origin	No
Blood or blood derivates	No
Medicinal substances	No
Heavy metals	No
PVC	No

Sterilization

Kliniderm Super Fiber + APTTM is sterilized by Gamma irradiation.

Storage conditions

The products should be stored at a temperature of maximum 30oC in a clean, dry environment.

Shelf life

2 years from production date, when stored under specified conditions.

Product Specifications

Approval	Name	Date	Signature
Associate Category and Product Development Manager Wound Care	Myrthe Engelen		
QA/RA Manager	Warsha Baboelal		