

# Product Specifications

Brand : Klinion® Woundcare

Product : Kliniderm® Super Fiber

## Product description

Kliniderm® Super Fiber dressings are single use, sterile nonwoven wound dressings, composed of 100% sodium carboxymethylcellulose fibers. This conformable and highly absorbent dressing absorbs wound exudate and transforms into a cohesive transparent gel, maintaining a moist environment to support the wound healing process and minimizing pain and discomfort to the patient during dressing changes or when the dressing is in situ. It absorbs and retains exudate to lock away harmful components contained within the wound exudate, such as bacteria and proteinases, reducing the risk of wound infection and maceration.

## Intended use

Kliniderm® Super Fiber dressings are indicated for the management of moderate to heavily exuding chronic and acute wounds which have breached the epidermis or dermis. The dressings may be used throughout the healing process on the following wounds:

- Leg ulcers
- Pressure ulcers (stage II-IV)
- Diabetic ulcers
- Donor sites
- Post-operative wounds
- Surgical wounds left to heal by secondary intent
- Partial thickness burns
- Abrasions
- Lacerations

## Classification

Class IIb under Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices).

# Product Specifications

## Packaging & Product Reference

Product Reference	Description	Sizes (*)	Piece(s)	Inner Carton	Outer Carton
40511806	Kliniderm® super fiber	5 x 5 cm	1 pc	10 pcs	960 (96 x 10)
40511807	Kliniderm® super fiber	10 x 10 cm	1 pc	10 pcs	640 (64 x 10)
40511808	Kliniderm® super fiber	15 x 15 cm	1 pc	5 pcs	280 (56 x 5)
40511809	Kliniderm® super fiber	2 x 45 cm	1 pc	5 pcs	360 (72 x 5)
40514810	Kliniderm® super fiber	1 x 45 cm	1 pc	5 pcs	360 (72 x 5)

\*Sizes are approximate

## Product & Packaging EAN code, dimension and weight Reference

Product Reference	Description	Sizes (*)	EAN piece(s)	EAN inner carton	EAN outer carton
40511806	Kliniderm® super fiber	5 x 5 cm	16942327009735	26942327009732	36942327009739
40511807	Kliniderm® super fiber	10 x 10 cm	16942327041513	26942327041510	36942327041517
40511808	Kliniderm® super fiber	15 x 15 cm	16942327041520	26942327041527	36942327041524
40511809	Kliniderm® super fiber	2 x 45 cm	16942327073392	26942327073399	36942327073396
40511810	Kliniderm® super fiber	1 x 45 cm	16942327077055	26942327077052	36942327077059

\*Sizes are approximate

Product Reference	Medeco article #	Description	Dimension peel pouch in cm	Dimension inner carton in cm	Dimension outer carton in cm
40511806	3069813	Klinion® Kliniderm® super fiber 5 x 5 cm	9 x 11	11.3 x 9.5 x 3.5	40.7 x 29 x 37.3
40511807	3069812	Klinion® Kliniderm® super fiber 10 x 10 cm	14 x 15.8	16.7 x 14.6 x 3.5	52.8 x 31.6 x 36.3
40511808	3069811	Klinion® Kliniderm® super fiber 15 x 15 cm	20 x 21	21.6 x 20.4 x 2.5	45.4 x 31.8 x 44
40511809	3069810	Klinion® Kliniderm® super fiber 2 x 45 cm	10 x 21	21.6 x 10.1 x 3.5	45.1 x 32.3 x 44.3
40511810	3073324	Klinion® Kliniderm® super fiber 1 x 45 cm	10 x 21	21.2 x 10.2 x 3	44.5x31x42.5

\*Sizes are approximate

# Product Specifications

Product Reference	Medeco article #	Description	Weight peel pouch INcl. product	Weight inner carton INcl. products	Weight outer carton INcl. products
40511806	3069813	Klinion® Kliniderm® super fiber 5 x 5 cm	4.5 gr	45 gr	5190 gr
40511807	3069812	Klinion® Kliniderm® super fiber 10 x 10 cm	8.3 gr	83 gr	6432 gr
40511808	3069811	Klinion® Kliniderm® super fiber 15 x 15 cm	19.4 gr	97 gr	6579 gr
40511809	3069810	Klinion® Kliniderm® super fiber 2 x 45 cm	11.6 gr	58 gr	5423 gr
40511810	3073324	Klinion® Kliniderm® super fiber 1 x 45 cm	3.48 gr	39.13 gr	3469.4 gr

\*Sizes are approximate

## Features

- Helps to minimize the risk of pain and damage to the wound at dressing changes.
- Absorbs and retains exudate to lock away harmful components, such as bacteria and proteinases.
- Comfortable for the patient.
- Supports moist wound healing.
- 100% sodium carboxymethylcellulose fibers.
- Single use up to 7 days wear time.
- No stitches, allowing optimal contact with the wound bed.

## Precautions

- In case of signs of infection, consult a healthcare professional for adequate infection treatment.
- Do not use on patients with a known sensitivity to the dressing or its components.
- Sterile if pouch and seal are intact. Do not use if damaged.
- Do not re-use. Re-use can cause serious infections.
- Do not re-sterilize.
- For external use only.
- For use under the guidance of a healthcare professional.

# Product Specifications

## Product components

Kliniderm® Super Fiber dressings consist of 100% sodium carboxymethylcellulose.

## Product performance specifications

Characteristics	Value
Free swell absorption	20.95g/100cm <sup>2</sup>
Product Base weight (GSM)	≥ 170± 30g/m <sup>2</sup>

## Presence of specific components

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

## Sterilization

Gamma sterilized.

## Storage conditions

The products should be stored under ambient conditions, in the original packaging. In a cool, dry and well-ventilated place, non-corrosive gas environment, away from direct sunlight, fire, and flammable materials.

## Shelf life

3 years from production date when stored under specified conditions.

# Product Specifications

Picture



Approval	Name	Date	Signature
Product Development Manager	Myrthe Engelen		
QA/RA-Manager	Warsha Baboelal		