

Product Specifications

Brand : Klinion®

Product : Kliniderm® Superabsorbent Dressing

Product description

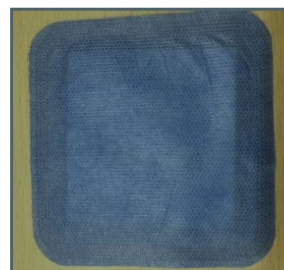
Kliniderm® Superabsorbent dressing (sterile) is an advanced wound dressing; the four layers construction makes it ideal for the moderate to heavily exuding wounds.

- The hydrophilic Polypropylene (PP) contact layer transmits fluid upwards and does not adhere to the wound-bed;
- The PP distribution layer provides rapid fluid uptake and distributes the exudate evenly into the absorbent layer;
- The central absorbent core contains superabsorbent polymer (SAP) particles for outstanding absorption and retention;
- The non-woven spun-melt-spun (SMS) fluid repellent backing layer minimizes fluid strike-through and its vapor permeable qualities improve breathability and exudate management property.

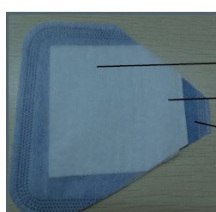
Kliniderm® Superabsorbent dressing (sterile) absorbs excess wound exudate through the contact layer, retains the exudate within the core and therefore minimises the risk for maceration. The fluid-repellent non-woven backing acts as a barrier and prevents exudate strike-through.



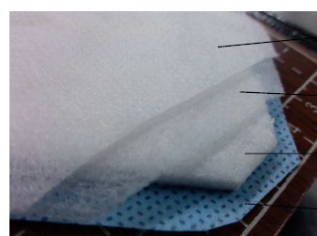
Front surface of product



Backing surface of product



Structure of different layers



- Hydrophilic PP nonwoven works as wound contact layer
- Distribution layer
- Absorbent core contains SAP polymer
- Water repellent SMS nonwoven works as backing layer

Kliniderm® Superabsorbent dressing sterile images

(Note: The backing surface of the Medeco superabsorbent dressing is green and not blue as in the pictures above)

Product Specifications

A specified number of dressings are placed inside a carton. The cartons are then placed in an outer corrugated case.

Intended use

Kliniderm® Superabsorbent dressings are indicated for moderate to heavily exuding chronic and acute wounds and may be used throughout the healing process on the following wounds:

- Leg ulcers
- Pressure ulcers
- Oncology wounds
- Post-operative wounds
- Traumatic wounds

Kliniderm® Superabsorbent dressing can remain in place for up to 7 days, dependent on patient condition and the level of exudate. Initially it may be necessary to replace Kliniderm® superabsorbent when the dressing has reached its absorbent capacity or whenever good wound care practice dictates that the dressing should be changed.

Kliniderm® Superabsorbent dressing is suitable for use under compression.

Classification

Class IIb under the Medical Devices Regulations (SI 2002 No. 618, as amended) and
Class IIb under the Regulation (EU) 2017/745 Medical Device Regulation (MDR).

Packaging & Product Reference

Product Reference	Description	Sizes (*)	Piece(s)	Inner Carton	Outer Carton
40511700	KLINIDERM SUPERABSORBENT DRESSING 7.5CM X 7.5CM	7.5CM X 7.5CM	1	50	400 (8 X 50)
40511706	KLINIDERM SUPERABSORBENT DRESSING 10CM X 10CM	10CM X 10CM	1	10	50 (5 X 10)
40511701	KLINIDERM SUPERABSORBENT DRESSING 10CM X 10CM	10CM X 10CM	1	50	400 (8 X 50)
40511707	KLINIDERM SUPERABSORBENT DRESSING 10CM X 15CM	10CM X 15CM	1	10	40 (4 X 10)
40511713	KLINIDERM SUPERABSORBENT DRESSING 10CM X 20CM	10CM X 20CM	1	10	240 (24 X 10)
40511702	KLINIDERM SUPERABSORBENT DRESSING 10CM X 20CM	10CM X 20CM	1	50	400 (8 X 50)
40511708	KLINIDERM SUPERABSORBENT DRESSING 15CM X 20CM	15CM X 20CM	1	10	40 (4 X 10)
40511703	KLINIDERM SUPERABSORBENT DRESSING 20CM X 20CM	20CM X 20CM	1	15	120 (8 X 15)
40511704	KLINIDERM SUPERABSORBENT DRESSING 20CM X 30CM	20CM X 30CM	1	10	80 (8 X 10)
40511705	KLINIDERM SUPERABSORBENT DRESSING 20CM X 40CM	20CM X 40CM	1	10	80 (8 X 10)

*Sizes are approximate

Product Specifications

Product Reference	Description	Sizes (*)	EAN Piece(s)	EAN Inner Carton	EAN Outer Carton
40511700	KLINIDERM SUPERABSORBENT DRESSING 7.5CM X 7.5CM	7.5CM X 7.5CM	8715343067277	8715343012642	8715343012659
40511706	KLINIDERM SUPERABSORBENT DRESSING 10CM X 10CM	10CM X 10CM	8715343067321	8715343021972	8715343021989
40511701	KLINIDERM SUPERABSORBENT DRESSING 10CM X 10CM	10CM X 10CM	8715343067284	8715343012666	8715343012673
40511707	KLINIDERM SUPERABSORBENT DRESSING 10CM X 15CM	10CM X 15CM	8715343067338	8715343021996	8715343022009
40511713	KLINIDERM SUPERABSORBENT DRESSING 10CM X 20CM	10CM X 20CM	8715343066157	8715343066164	8715343066171
40511702	KLINIDERM SUPERABSORBENT DRESSING 10CM X 20CM	10CM X 20CM	8715343067291	8715343012680	8715343012697
40511708	KLINIDERM SUPERABSORBENT DRESSING 15CM X 20CM	15CM X 20CM	8715343067345	8715343022016	8715343022047
40511703	KLINIDERM SUPERABSORBENT DRESSING 20CM X 20CM	20CM X 20CM	8715343067307	8715343012710	8715343012741
40511704	KLINIDERM SUPERABSORBENT DRESSING 20CM X 30CM	20CM X 30CM	8715343067314	8715343012758	8715343012765
40511705	KLINIDERM SUPERABSORBENT DRESSING 20CM X 40CM	20CM X 40CM	8715343048290	8715343048313	8715343048344

Features

- Suitable for heavily exuding wounds
- Effective moisture uptake and distribution
- Comfortable
- Non-adherent wound contact layer
- Can remain in place for up to 7 days
- Suitable for use under compression
- High permeability and allows effective vapour transfer
- Prevents exudate strike-through
- Rapid fluid uptake
- Prevents maceration of the surrounding skin by retaining the wound exudate within the core

Product Specifications

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 polypropylene, cellulose or SAP polymer.
- 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.

Contra-indications

- Do not cut or tear the dressing.
- Do not use on dry, non-exuding or lightly exuding wounds.
- Do not use as a treatment for arterial bleeding or on heavily bleeding wounds.
- Do not use in cavity wounds or for surgical implantation.
- Do not use on third-degree burns.

Specifications

Layer	Material	Color
1. Bottom Layer (contact layer)	PP non-woven	White
2. Distribution layer	PP non-woven	White
3. Inner layer (central absorbent core)	Superabsorbent polymer (sodium polyacrylate)	White
4. Top layer (fluid repellent backing layer)	Spun-melt-spun non-woven	Green

Product Specifications

Performance Characteristic	Specification	Test Methods
Appearance	No damage	Visual
Size of the dressing	Nominal $\pm 10 \%$	ISO 22198:2006
Size of the superabsorbent layer	Nominal $\pm 10 \%$	ISO 22198:2006
Residual monomer in the superabsorbent	≤ 100 ppm	Supplier method
Fluid absorption	≥ 50 g / 100 cm ²	EN 13726-1:2002/AC:2003
Fluid retention	≥ 20 g / 100 cm ²	EN 13726-1:2002/AC:2003
MVTR	≥ 10000 g / (m ² 24 h)	EN 13726-2:2002
Edge sealing strength	≥ 10 N / 5 cm	YY/T 0681.2 (note: sample width is 5cm)
Pouch appearance	Clean peel	Visual and inspection by hand
Pouch dye penetration	No penetration	EN ISO 11607-1:2009
Pouch Seal strength	≥ 0.75 N / 15 mm	EN ISO 11607-1:2009
Pouch Seal width	≥ 6 mm	ISO 22198:2006
Sterility testing	Negative	European Pharmacopeia Chapter 2.6.1 sterility

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

Product Specifications

Sterilization

EO sterilized.

Storage conditions

Kliniderm® Superabsorbent dressing (sterile) should be stored in the original packaging, in a cool, dry and well-ventilated room, away from direct sunlight.

Shelf life

Kliniderm® Superabsorbent dressing (sterile) has a shelf life of 3 years from production date, when stored under specified conditions.

Picture



Product. ref.: 40511707

Approval	Name	Date	Signature
Global Product Manager Wound Care	Myrthe Engelen		
RA Specialist	Alexandra Duarte		