SUPRASORB® G
Gel Wound Dressing

REF 33630 - 33632

May 2016

Translation: Peritus
Revision: MI / M. Fuchs

1. Composition of the product

The SUPRASORB® G Gel Wound Dressing consists of:

-	Backing film	Polyethylene, transparent
-	Hydrogel layer	Polyethylene matrix, blue Water Acrylic polymer based on a taurate derivative phenoxyethanol
-	Release film	Polyethylene film, white

This product data sheet covers the following items:

REF 33630	Suprasorb® G Gel Wound Dressing	5 x 6.5 cm	5 pcs./ SC
REF 33631	Suprasorb® G Gel Wound Dressing	10 x 10 cm	5 pcs./ SC
REF 33632	Suprasorb® G Gel Wound Dressing	20 x 20 cm	3 pcs./ SC

2. Packaging, structure, and composition

2.1 Unit Container

- Peel pouch consisting of cellulose, polyethylene and aluminium

2.2 Shelf Container

- Cellulose folding box
- Instructions for use, made from cellulose

2.3 Transit Container

- Corrugated cardboard box made from cellulose

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Location: Moldova

3. Manufacture

The SUPRASORB® G Gel Wound Dressing is manufactured to specification under hygienic conditions and packaged as described in its respective packaging specifications.
The device is sterilized by radiation in compliance with DIN EN ISO 11137 part 1-3.

4. Description

SUPRASORB® G Gel Wound Dressing is a non-adhesive, high water content hydrogel dressing. It is a two-sided, clear, transparent hydrogel formed around a supporting blue polyethylene matrix.
The product contains approximately 70% water with the remaining 30% consisting of a swollen acrylic polymer based on a taurate derivative with phenoxyethanol as a preservative.

5. Properties (see valid instructions for use)

SUPRASORB® G Gel Wound Dressing provides a moist environment at the surface of the wound. The gel is permeable to water vapour and gases.

Indications:
SUPRASORB® G Gel Wound Dressing may be used as a wound contact layer, providing cooling and soothing as well as exudate absorption and retention.
Primarily for burns, scalds, radiation therapy damage, epidermal damage and leg ulcers. To manage nociceptive wound pain, to assist in autolytic debridement by hydration of necrotic and sloughy tissue. Suitable for use on painful wounds. It may be used with secondary dressings where appropriate.
SUPRASORB® G Gel Wound Dressing can be used under compression on moderate to highly exuding wounds. SUPRASORB® G Gel Wound Dressing is indicated in superficial burns up to middermal level, which includes epidermal and superficial partial thickness.

Contraindications:
SUPRASORB® G Gel Wound Dressing is not indicated for:

- Heavily bleeding wounds
- Third degree burns
- Insert for deep narrow cavities or sinuses
- Patients with a known sensitivity to any of the dressing components

6. Medical device classification

The SUPRASORB® G Gel Wound Dressing is a medical device of Class IIb in terms of Rule 4.
(Council Directive 93/42/EWG concerning medical devices, Annex IX)

7. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of SUPRASORB® G Gel Wound Dressing are safe if the product is used for the purposes intended.

The purpose of this documentation and the statements made herein is to show that there is no risk involved in the use of the product SUPRASORB® G Gel Wound Dressing and that it is designed, manufactured, and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

8. Stability

Stored appropriately, the product has a shelf life of 3 years.

9. Disposal

The user is advised to observe current national legislation, norms, and guidelines regulating the disposal of medical waste.
Packaging materials must also be disposed of in compliance with applicable national requirements.

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Signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)