

SUPRASORB® A

Calcium alginate dressing, sterile

REF 20440 - 20442, 20445

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1. Composition of the product

SUPRASORB® A Calcium alginate dressings and ropes consist of:

- Calcium alginate fibers

This product data sheet covers the following items:

REF 20440	Suprasorb® A Calcium alginate dressings	5 x 5 cm, sterile
REF 20441	Suprasorb® A Calcium alginate dressings	10 x 10 cm, sterile
REF 20442	Suprasorb® A Calcium alginate dressings	10 x 20 cm, sterile
REF 20445	Suprasorb® A Calcium alginate ropes	30 cm/2 g, sterile

2. Packaging, structure and composition

2.1 Unit container

- peel pouch consisting of cellulose and polyethylene

2.2 Shelf container

- folding box (cellulose)
- instructions for use (cellulose)

2.3 Transit container

- corrugated cardboard box (cellulose)

3. **Manufacture**

SUPRASORB® A calcium alginate dressings and ropes is produced according to specification in hygienic conditions, packed as described in its relevant packaging specification, and sterilized by radiation in compliance with DIN EN ISO 11137, parts 1-3.

4. **Description**

SUPRASORB® A calcium alginate dressings and packing are cream-colored, nearly odorless, and manufactured from non-woven needled fibers (dressings) or from a rope assembly of fibers (packing).
The dressings are available in various sizes.

5. **Properties**

The calcium alginate fibers react with wound exudate or blood and form a gel which promotes a moist wound environment.
The medical devices are intended for single use only and must not be resterilized.
The products are sterile unless the packaging has been damaged or opened.

6. **Intended purpose** (see valid instructions for use)

SUPRASORB® A calcium alginate dressings and ropes is indicated for the treatment of the following wounds: decubitus ulcers, arterial ulcers, lower leg venous ulcers, diabetic ulcers, split-thickness skin removal sites if they have heavy exudate and are superficial or deep.

7. **Medical device classification**

SUPRASORB® A calcium alginate dressings and ropes is a medical device of Class IIb in terms of Rule 4.
(Council Directive 93/42/EEC concerning medical devices, Annex IX)

8. **Biological evaluation and biocompatibility** (DIN EN ISO 10993)

The starting materials used in the manufacture of SUPRASORB® A calcium alginate dressings and packing are safe if the product is used appropriately and for the purposes intended.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device SUPRASORB® A calcium alginate dressings and packing 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.

9. Stability

Stored appropriately – not more than 25°C - SUPRASORB® A calcium alginate dressings and ropes have a shelf life of 5 years in the unopened original packaging.

10. Disposal

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

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signed by
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