

Suprasorb® A + Ag

Antimicrobial Calcium Alginate Wound Dressing, sterile

REF 20570 – 20573, 121902, 121903, 101915

December 2017

Update: S. Golz

1. Composition of the product

Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile and Ropes consist of a uniform blend of:

- calcium alginate fibres
- silver alginate fibres

The alginate fibres consist of mannuronic acid and of guluronic acid.

This product data sheet covers the following items:

REF	Product description	Size	Stk/ SC
20570	Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile	5 x 5 cm	10
121902	Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile	5 x 5 cm	8
20571	Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile	10 x 10 cm	10
121903	Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile	10 x 10 cm	8
20572	Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile	10 x 20 cm	5
20573	Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile	30 cm / 2 g	5
101915	Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile	30 cm / 2 g	5

2. Packaging, structure and composition

2.1 Unit container

REF 20570, 121902, 20571, 121903, 20572, 101915

- peel pouch consisting of cellulose, ethylencopolymer, aluminium and ethylene

REF 20573

- deep draw pack consisting of cellulose, a polyethylene coating and modified polystyrene

2.2 Shelf container

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

2.3 Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

Suprasorb® A + Ag Antimicrobial calcium alginate wound dressings and Ropes are produced according to specification in hygienic conditions, packed as described in their relevant packaging specification. The product is sterilized by gamma irradiation in compliance with DIN EN ISO 11137, part 1-3.

4. Description

Beige to light-brown dressings made of a non-woven needled fabric respectively rope made of a rope assembly.

5. Properties

Suprasorb® A + Ag Antimicrobial calcium alginate wound dressings and Ropes are soft, conformable wound covers with a high mannuronic acid content. The silver-impregnated calcium alginate fibres react with wound exudate or blood to form a gel which creates a moist wound environment. The silver contained in the wound dressing has broad antimicrobial activity, including against MRSA and VRE (spectrum of pathogens in vitro, see instructions for use). In vitro, 5,5 ppm/10 cm² (wound dressing) of the ionic silver is released from the silver alginate fibres (1,5%) within 24 h. The high exudate absorption capacity promotes wound healing. Suprasorb® A + Ag Antimicrobial calcium alginate wound dressings and Ropes are individually sterile packed and sterilised by irradiation. The products are sterile unless the packaging is open or damaged.

Suprasorb® A + Ag Antimicrobial calcium alginate wound dressings / packing rope are for single use only and must not be resterilised.

6. Intended purpose (see valid instructions for use)

Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, sterile and Ropes can be used for the treatment of at risk of infection and infected wounds.

7. Medical device classification

Suprasorb® A + Ag Antimicrobial calcium alginate wound dressing, and Ropes are medical devices of Class III in terms of Rule 13.
(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 + Ag Antimicrobial calcium alginate wound dressing, and rope are safe when the product is used appropriately and for the intended purpose.

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 + Ag Antimicrobial calcium alginate wound dressing and Ropes 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

Do not store above 25 °C, do not freeze or refrigerate. Stored appropriately the product has a shelf life of 3 years.

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.

Lohmann & Rauscher International GmbH & Co. KG
D-56579 Rengsdorf
signed by
Dr. Annette Koggel
Quality & Regulatory Affairs