



Suprasorb® A + Ag Pro

Antimicrobial Calcium Alginate Wound Dressing / Rope with Silver

Pathogen spectrum detected in vitro:

Bacteria:

Pseudomonas aeruginosa¹
Klebsiella pneumoniae¹
Escherichia coli¹
Staphylococcus aureus¹
Staphylococcus aureus (MRSA)¹
Streptococcus pyogenes¹
Staphylococcus epidermidis¹
Staphylococcus epidermidis (MRSE)¹
Vancomycin Resistant Enterococcus (VRE)¹
Enterococcus faecalis³
Proteus vulgaris²
Enterobacter cloacae²
Acinetobacter baumannii²

Fungi:

Candida albicans³

¹ Spectrum of antimicrobial activity demonstrated in vitro on Suprasorb® A +Ag Pro over a period of seven days (ASTM E2149)

² Demonstrated by in vitro investigations on a comparable product

³ Spectrum of antimicrobial activity demonstrated in vitro on Suprasorb® A +Ag Pro over a period of three days (ASTM E2149)

en Instructions for Use

Product description

Suprasorb® A + Ag Pro Antimicrobial Calcium Alginate with Silver Wound Dressings and Rope are soft, conformable wound coverings with a beige to light brown colour, made of a fabric blend between calcium alginate fibres, silver alginate fibres and strengthening cellulose fibres, providing a strengthened fabric dressing, with gelling fibres, which retain wound exudate. If required, can be used in conjunction with a suitable moisture-retaining secondary dressing to keep the product in place and/or under compression. When dry, the wound dressings can easily be cut to the size of the wound.

The silver-impregnated calcium alginate fibres have a high mannuronic acid content and 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*. Antimicrobial action (> 3 log steps) associated with the ionic silver from the silver alginate fibres (1.5%) is observed in vitro after just 24 h and this remains stable for up to seven days*.

The high vertical absorption of exudate into the fibre dressing protects the wound environment and the wound edge, thus supporting the healing process.



Suprasorb® A + Ag Pro Antimicrobial Calcium Alginate with Silver Wound Dressings / Rope are individually sterile packed and sterilised by irradiation. The products are sterile as long as the packaging is unopened and undamaged. The products are for single use only and must not be re-sterilised.

Product composition

Suprasorb® A + Ag Pro Antimicrobial Calcium Alginate with Silver Wound Dressings / Rope consist of a homogeneous combination of 20% cellulose fibres, 74% calcium alginate fibres and 6% silver alginate fibres (1.5% ionic silver). The alginate fibres are composed of around 60% mannuronic acid and around 40% guluronic acid.

Intended use

Suprasorb® A + Ag Pro Antimicrobial Calcium Alginate with Silver Wound Dressings / Rope can be used for the treatment of wounds at risk of infection and infected wounds.

Indications

Suprasorb® A + Ag Pro Antimicrobial Calcium Alginate with Silver Wound Dressings / Rope can be used for the treatment of wounds at risk of infection and infected wounds which are



heavily exuding



superficial or



deep, for

- pressure ulcers
- arterial ulcers
- venous lower leg ulcers
- diabetic ulcers
- post-operative wounds
- skin graft and donor sites

Contraindications

Do not use in cases of hypersensitivity to the product or any of their components; dry wounds.
* Pathogen spectrum detected in vitro, see first column of the Instructions for Use.

Side effects

In very rare cases skin irritations or allergies may occur. Maceration or pain on removing the dressing has been described in isolated cases with this product group.

Application

1. Preparing the wound:

Clean the wound carefully in accordance with current clinical standards. The skin surrounding the wound should be clean and dry.

2. Applying the wound dressing:

The size of the dressing depends on the wound size.

a. The size of the dressing should match the wound area. Keep the product away from the wound while cutting it to size. If required, the wound dressing and packing rope may be cut to size with sterile scissors.



- b. Open the sterile packaging and remove the dressing under aseptic conditions.
- c. Place the dressing on the moist wound, overlapping the wound edges by approximate 1 cm. If there is a low amount of exudate present, moisten the dressing with physiological saline solution (0.9%).
- d. Loosely pack deep wounds with the rope. For deep wounds use the Rope format.
- e. Pack wounds lightly and leave approximate 2.5cm overlapping the wound edges.
- f. Apply a suitable moisture-retaining secondary dressing to keep the product in place.
- g. If required, the wound dressing and packing rope may be cut to size with sterile scissors.
- h. Secure the Wound Dressing / Rope with a suitable secondary dressing.

3. Dressing change:

- a. Remove the secondary dressing in accordance with current clinical standards.
- b. Remove the non-gelled part of the product and rinse out any gel left behind in the wound with physiological saline solution (0.9%) before assessing the wound and applying a new dressing.

The dressing should be changed when medically indicated (e.g. when the dressing has reached its absorbent capacity or whenever good wound care practice dictates a change is needed), determined by the treating physician. Depending on the level of exudate, Suprasorb® A + Ag Pro can remain on/in the wound for up to 7 days. The interval between changes should be no more than 7 days. The product can be removed using e.g. sterile forceps. Should the dressing adhere to wounds with lower exudate levels, moisten it with physiological saline solution (0.9%) before changing the dressing so that the healing process is not disturbed.

Any gel residue on the wound should be removed when cleansing the wound. Wound cavities in particular should be well irrigated. The treatment should be discontinued after 30 days. Dispose in accordance with local guidance.

Precautions

- Suprasorb® A + Ag Pro Antimicrobial Calcium Alginate with Silver Wound Dressings / Rope must be used under medical supervision.
- Wounds must be assessed and managed appropriately, as indicated, under the supervision of a medical professional.
- If signs of an allergic reaction are detected, discontinue the use of the product and seek advice from a healthcare professional on the next course of action.
- No data are available concerning compatibility with topical preparations.
- Avoid contact with electrodes or conductive gels during electrical measurements (e.g. EEG or ECG).
- Do not use on patients undergoing magnetic resonance imaging (MRI).
- Application in the case of heavily bleeding wounds, during pregnancy or lactation or for children, infants or newborns is decided on by the treating physician. At present, no documented clinical experience with the product in such cases is available. Indication for adults patients only.
- Suprasorb® A + Ag is not intended to be used on wounds with severe bleeding, inside internal body cavities or closed wounds.

When treating infected wounds, the wound dressing should not be the only therapeutic measure used, but rather should be supplemented by drug therapy at the discretion of the treating doctor in accordance with local clinical protocols.

The use of the dressing on infected wounds does not negate the need to follow local practices with regards to infection management and use of the systemic antibiotics.

In general, the use of a suitable primary or secondary dressing is at the discretion of the treating physician and depends on the patient's general situation.



In the case of infected wounds, the treating physician will decide on the basis of the patient's general condition whether an occlusive secondary dressing can be applied.

Storage instructions

Do not freeze or refrigerate! Store between 5- 25°C.



Do not freeze or refrigerate



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Packaging Version **4043163/2021-05**