

CuraFoam™ AG

Silver Foam Dressings

Non-Bordered



CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician



INSTRUCTIONS FOR USE

Description

CuraFoam™ AG Silver Foam Dressing mainly includes polyurethane foam, polyvinyl alcohol, silver sulfate and silver chloride. It is a highly absorbent foam dressing with ionic silver as the active component. The dressing provides an optimal moist wound healing environment, combining an effective antibacterial activity in the dressing with exudates management. The dressing has broad spectrum antibacterial effect for Gram positive and Gram negative bacteria. It has been shown to have 4 log bacterial reductions up to 7 days in vitro against the following bacteria: *Staphylococcus aureus*, *Streptococcus pyogenes*, *Enterococcus faecalis*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. CuraFoam™ AG Silver Foam Dressing is available in various sizes and shapes. The dressings are packaged in individual bags.

Indications

CuraFoam™ AG Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds, including leg ulcers, pressure ulcers, diabetic ulcers, first and second-degree burns, donor sites, post-operative wounds and skin abrasions.

Contraindications

1. Do not use CuraFoam™ AG Silver Foam Dressing on patients with known sensitivity to silver.

Product Information:

| | |
|------------------------------|--|
| Antibacterial Agent: | Silver sulfate and silver chloride |
| Spectrum of Activity: | Broad spectrum antibacterial effect for Gram positive & Gram negative bacteria |
| Concentration on the device: | Each dressing contains 0.35~0.40mg/cm ² silver |

In Vitro Study Results:

The device is non-irritating, non-cytotoxic and biocompatible in a wound environment. The device is tested for antibacterial activity for up to 168 hours. The device has broad spectrum antibacterial effect for Gram positive and Gram negative bacteria.

| Bacterial | <i>Staphylococcus aureus</i> | <i>Streptococcus pyogenes</i> | <i>Enterococcus faecalis</i> |
|----------------------|------------------------------|-------------------------------|-------------------------------|
| | ATCC 6538 | ATCC 19615 | ATCC 29212 |
| 168 Hour % Reduction | >99.99% | >99.99% | >99.99% |
| Bacterial | <i>Escherichia coli</i> | <i>Klebsiella pneumoniae</i> | <i>Pseudomonas aeruginosa</i> |
| | ATCC 8739 | ATCC 4352 | ATCC 9027 |
| 168 Hour % Reduction | >99.99% | >99.99% | >99.99% |

Instructions for Use

1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size dressing to cover the wound area.
3. Cover and secure the CuraFoam™ AG Silver Foam Dressing with a secondary dressing.
4. Dressing change frequency will depend on patient condition and the level of exudates. Initially it may be necessary to change the dressing every 24 hours. When the exudates reduce, the frequency may decrease.
5. Gently remove the secondary dressing. If the wound appears dry, saturate the dressing with sterile saline water prior to removal.

Warnings

1. This product is for single use. Do not use if pouch is damaged or open.
2. Do not use this product on a dry wound.
3. Frequent or prolonged use of this product may result in permanent discoloration of the skin.
4. The silver is only present as a preservative within the dressing.
5. CuraFoam™ AG Silver Foam Dressing is intended for short-term use and should not be used for more than 28 days over multiple dressing changes.
6. Reduction in colonization or microbial growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

Specifications: 4" x 4" (10 cm x 10 cm), Non-Bordered

Shelf life: 3 years from date of manufacture.

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Made in China R180620



SYMBOL GLOSSARY
For an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php