

ComfortFoam/AgTM

FOAM WOUND DRESSING WITH SOFT SILICONE ADHESIVE AND SILVER

For the management of exuding wounds

DESCRIPTION

ComfortFoam/Ag absorbs exudate, maintains a moist wound healing environment and has antibacterial preservative properties. ComfortFoam/Ag foam dressing consists of 0.25~0.35mg/cm² of silver ions that demonstrate in vitro antibacterial preservative effectiveness within the dressing for up to 7 days.

ComfortFoam/Ag consists of a vapor permeable waterproof polyurethane top film, an absorbent polyurethane foam pad containing polyvinyl alcohol, silver sulfate and silver chloride with a soft silicone wound contact surface.

INDICATIONS FOR USE

ComfortFoam/Ag is indicated for the management of exuding wounds, such as leg and foot ulcers, pressure ulcers, traumatic and surgical wounds, superficial and partial thickness burns. Silver compounds present in the dressing help reduce bacterial colonization in the dressing.

CONTRAINDICATIONS

ComfortFoam/Ag should not be used on patients with a known sensitivity to silver or any other contents of the dressing.

DIRECTIONS (Use under the guidance of a healthcare professional.)

PREPARE WOUND SITE AND SURROUNDING SKIN:

1. Cleanse wound with sterile saline or sterile water to remove residue according to local infection control protocol. Deep wounds should be well irrigated.
2. Skin around wound should be clean and dry, use skin barrier prep as needed.

TO APPLY:

1. Remove dressing from package.
2. Dressing may be cut to size prior to application.
3. Remove backing paper from dressing.
4. Apply sticky side of dressing to moist wound bed overlapping 1-2 inches of dry skin; gently smooth into place.
5. Secure edges with tape if desired.

CHANGING THE DRESSING:

- Dressing may be left in place for up to 7 days.
- Change the dressing if drainage shows through the back of the dressing, or if the edge of the dressing becomes loose; or if the condition of the wound or surrounding skin causes concern; or as directed by a qualified healthcare professional.
- Dressing may be moistened to ease removal.
- Carefully remove adhesive dressings by holding the edge of the dressing and slowly pulling it parallel to the skin.
- Dispose of in accordance with local guidance.

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WARNINGS


- For single use only.
- Sterile. Do not use if the pouch is damaged or opened prior to use.
- Not recommended for use on dry wounds.
- Do not use ComfortFoam/Ag together with oxidants, such as hypochlorite solutions or hydrogen peroxide.
- ComfortFoam/Ag may cause transient discoloration of the wound bed and surrounding skin. Frequent or prolonged use of this product may result in permanent discoloration of skin.
- ComfortFoam/Ag does not replace the need for systemic therapy or other adequate infection treatment in the event of clinical infection.
- Do not use ComfortFoam/Ag during radiation treatment or examinations, such as X-ray, magnetic resonance imaging [MRI], ultrasound or diathermy. ComfortFoam/Ag is MRI unsafe.
- Avoid contact with electrodes or conductive gels during electronic measurements, such as electrocardiograms [ECG], and electroencephalograms [EEG].
- For external use only.
- The silver is only present as a preservative within the dressing.
- ComfortFoam/Ag is intended for short-term use up to 28 days.
- 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.

STORAGE AND DISPOSAL:

- Store the product in a cool, dry place. Avoid light.

SHELF LIFE: 2 years from date of manufacture

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed healthcare practitioner).

DEPTH / STAGE	ABSORBENCY
PARTIAL FULL	
1 2 3 4	HIGH
For Partial and Full thickness wounds / Pressure ulcers stages 2-4	

Rx Only

DermaRite®