DermaGinate/Ag is a calcium alginate wound dressing with antibacterial silver composed of calcium alginate, sodium alginate, and silver particles. DermaGinate/Ag is made of natural fibers derived from seaweed, and is designed to be highly absorbent. The dressing absorbs exudate and forms a gel-like surface over the wound that supports a moist wound healing environment and keeps the dressing from adhering to the wound. DermaGinate/Ag Silver Alginate Dressing can restrain bacterial growth within the dressing for 24 hours. DermaGinate/Ag Silver Alginate Dressing has been tested in vitro and found to be effective against bacteria such as: *Staphylococcus aureus*, *Streptococcus pyogenes*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, and *Staphylococcus epidermis*.

**INDICATIONS FOR USE**

**OTC:** May be used as first aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.

**PRESCRIPTION:** May be used as a primary wound dressing for moderate to heavily exuding partial to full thickness wounds, including: postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, and graft and donor sites.

**CONTRAINDICATIONS**

DermaGinate/Ag should not be used on patients with a known sensitivity to silver. Not intended for use on third degree burns.

**PRODUCT INFORMATION:**

<table>
<thead>
<tr>
<th>Preservative Agent</th>
<th>Silver particles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Against Pathogens:</td>
<td>Gram positive and Gram negative bacteria</td>
</tr>
<tr>
<td>Spectrum of Activity:</td>
<td>In vitro test results show antibacterial preservative effect for 24 hours against Gram positive and Gram negative bacteria such as <em>Escherichia coli</em>, <em>Klebsiella pneumonia</em>, <em>Pseudomonas aeruginosa</em>, <em>Staphylococcus aureus</em>, <em>Staphylococcus epidermidis</em>, and <em>Streptococcus pyogenes</em>.</td>
</tr>
<tr>
<td>Concentration on the device:</td>
<td>Each 100 mm x 100 mm dressing contains 16.0 mg (1.4% w/w) silver particles</td>
</tr>
</tbody>
</table>

**DIRECTIONS** (Please use under the guidance of a healthcare professional.)

**PREPARE WOUND SITE AND SURROUNDING SKIN:**

1. Cleanse wound with advised liquid 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. Choose a dressing size that can cover the wound bed. Remove from package. May be cut to size prior to application to fit wound bed.
2. Apply dressing to moist wound bed. Loosely pack deep wounds.
3. Secure with appropriate cover dressing that manages drainage and maintains a moist wound environment.
CHANGING THE DRESSING:

- Change the dressing daily or as needed depending on patient condition and level of exudate. When the exudate level decreases, the frequency of change may decrease.
- Change the dressing if drainage seeps 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.
- Gently remove the secondary dressing. Carefully remove adhesive dressings by holding the edge of the dressing and slowly pulling it parallel to the skin.
- If the wound appears dry, saturate the dressing with sterile saline or sterile water prior to removal.
- Dispose of in accordance with local guidance.

WARNINGS

- This product is single use. Do not use if pouch is damaged or open.
- Not suggested for use on dry wounds.
- The dressing should be changed daily to avoid colonization of the dressing.
- Frequent or prolonged use of this product may result in permanent discoloration of skin.

ADVERSE REACTIONS

DermaGinate/Ag Silver Alginate Dressing has been tested for in-vitro biocompatibility, including cytotoxicity, sensitization, skin irritation and systemic toxicity. All tests were performed in accordance with the ISO 10993 Standard Series for Biological Evaluation of Medical Devices. The results of these studies indicate that DermaGinate/Ag Silver Alginate Dressing is safe for its intended use.

OTHER INFORMATION

- Store product in a sealed, cool, dry place away from direct light.
- Not made with natural rubber latex.
- Shelf life: 2 years from date of manufacture.