### Product Name

KALTOSTAT® Calcium-Sodium Alginate Wound Dressing

### Product Sizes

<table>
<thead>
<tr>
<th>Dressing size:</th>
<th>Pack size:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.5cm x 12cm</td>
<td>10</td>
</tr>
<tr>
<td>10cm x 20cm</td>
<td>10</td>
</tr>
<tr>
<td>15cm x 25cm</td>
<td>10</td>
</tr>
<tr>
<td>2g rope</td>
<td>5</td>
</tr>
<tr>
<td>5cm x 5 cm</td>
<td>10</td>
</tr>
<tr>
<td>30cm x 60cm</td>
<td>5</td>
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</tbody>
</table>

### Product Description

Kaltostat® Wound Dressing is a soft, white-to-off-white, sterile non-woven pad or ribbon/rope dressing of calcium-sodium alginate fibre. The alginate fibres absorb wound exudate or saline and convert to a firm gel/fibre mat. This gel forms a moist, warm environment at the wound interface. The gel allows trauma-free removal with little or no damage to newly formed tissue. Depending upon the wound, the dressing may be left in place for up to seven days. Upon contact with a bleeding wound, Kaltostat promotes haemostasis. This primary dressing should be used with a secondary cover dressing.

### Indications

Kaltostat is an external wound dressing designed to absorb exudate and promote haemostasis.

Kaltostat Wound Dressing is indicated as an external wound dressing for the management of moderate to heavily exuding wounds such as:

- pressure ulcers, venous stasis ulcers, arterial ulcers, diabetic ulcers and oncology wounds
- donor sites, post surgical incisions, traumatic wounds and superficial burns
- Kaltostat is also indicated for the local management of bleeding wounds: lacerations, abrasions, nose bleeds, dental extractions, and after surgical wound debridement

### Contraindications

Kaltostat Wound Dressing should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components. Kaltostat is not indicated for third degree burns or for use as a surgical sponge.

Kaltostat Wound Dressing is not indicated for heavily bleeding wounds.
Precautions/Warnings

- Should you observe irritation (reddening, inflammation), maceration (whitening of skin), hypergranulation (excess tissue formation) or sensitivity (allergic reaction), consult a healthcare professional.
- Kaltostat Wound Dressing is designed to create a moist environment that assists in wound healing. If a Kaltostat Wound Dressing has initially formed a gel that is allowed to dry out, removal from the wound can be difficult. Drying out is generally not a problem with exuding wounds. Kaltostat Wound Dressing should be removed only with sterile normal saline. Reapplying saline may be necessary to maintain the gel. If the gel dries out, saturate the dried gel with saline to re-hydrate it; this process can take several hours to soften the dried gel.
- The dressing may be used on infected wounds only under the care of a healthcare professional.
- Appropriate supportive measures should be taken where indicated (e.g. use of graduated compression bandaging in the management of venous leg ulcers or pressure relief measures in the management of pressure ulcers).
- Colonization of chronic wounds is common and is not a contraindication to the use of the dressing. The dressing may be used on infected wounds under medical supervision together with appropriate therapy and frequent monitoring of the wound.
- The control of blood glucose, as well as appropriate supportive measures, should be provided with diabetic foot ulcers.
- For oncology wounds, a secondary dressing of high absorbency is recommended.
- In cavity wounds, the ribbon/rope dressing may be used to pack the wound. For wounds such as fistulae and sinus tracts, employ appropriate techniques during the insertion and removal of the dressing.
- Kaltostat Wound Dressing is not intended for use as a surgical sponge. Kaltostat is not intended to control heavy bleeding. Alternative measures must be considered in those emergency situations where large quantities of blood may be lost.

Application/Removal

1. Wound Site Preparation and Cleansing
   Before applying Kaltostat Wound Dressing, cleanse the areas with an appropriate wound cleanser.

   Under the care of a healthcare professional, if necessary, before applying Kaltostat Wound Dressing, the wound should be debrided of excessive necrotic tissue and eschar and irrigated with an appropriate non-toxic cleansing solution.

2. Dressing Preparation and Application
   a) Kaltostat Wound Dressing should be trimmed to the size of the wound.
   b) For moderately and heavily exuding wounds, Kaltostat Wound Dressing should be applied dry onto the wound. An appropriate secondary dressing should be used to secure Kaltostat Wound Dressing in place.
   c) When used on lightly exuding wounds, Kaltostat Wound Dressing should be placed on the wound and moistened with sterile normal saline. An appropriate secondary dressing should be used to secure Kaltostat Wound Dressing in place.

3. Dressing Change and Removal
   a) On moderately and heavily exuding wounds, change the Kaltostat Wound Dressing when strike-through of the secondary dressing occurs or whenever good clinical practice so dictates.
   b) Removal should be trouble free on heavily exuding wounds. Kaltostat Wound Dressing will gel at the wound/dressing interface and lift away.
c) Removal from lightly exuding wounds may be assisted by saturating the dressing with sterile normal saline.

d) Before applying Kaltostat Wound Dressing, cleanse the area with an appropriate wound cleanser.

e) As with any dressing, Kaltostat Wound Dressing should be removed from the wound and the wound cleansed at appropriate intervals in accordance with Good Clinical Practice, or up to a maximum of seven days.

4. **Bleeding Wounds**

   Apply Kaltostat Wound Dressing to the bleeding area to promote haemostasis. Remove carefully when the bleeding has stopped. Apply additional Kaltostat Wound Dressing as outlined above.

Discard any unused portion of the product after dressing the wound.

If the immediate product packaging is damaged, do not use.

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See insert for full instructions for use

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**Storage Conditions**

- Store in a cool, dry place
- Protect from light.

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**Shelf Life**

- 3 years