(ADHESIVE) HYDROGEL SHEET with LEPTOSPERMUM HONEY WOUND & BURN DRESSING MEDIHONEY Hydrogel

INSTRUCTIONS FOR USE

STERILE R Gamma Sterilized

For single use



Store at Room Temperature

Not made with natural rubber latex.

PRODUCT DESCRIPTION

MEDIHONEY[®] Adhesive Hydrogel Sheet Dressing with *Leptospermum* Honey is a moist wound dressing made of *Leptospermum* Honey (+15) in combination with a hydrogel gelling agent, surrounded by an adhesive border. The gelling agent is contained within the dressing mass. The dressing contains 100% *Leptospermum* Honey. As wound exudate is absorbed, the dressing – which has a low pH and high osmolarity – forms a gel. This assists in maintaining a moist environment for optimal wound healing, aids in autolytic debridement, and allows for non-traumatic removal. This product is an occlusive dressing, and does not require a secondary dressing.

INDICATIONS

Under the supervision of a healthcare professional, MEDIHONEY® Adhesive Hydrogel Sheet Dressing with *Leptospermum* Honey provides a moist environment conducive to wound healing and is indicated for non-draining to lightly exuding wounds such as:

- Diabetic foot ulcers
- Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- Pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- Donor sites, and traumatic and surgical wounds

CONTRAINDICATIONS

MEDIHONEY® Adhesive Hydrogel Sheet Dressing with *Leptospermum* Honey is not indicated for:

- Third degree burns
- Patients with a known sensitivity to honey

PRECAUTIONS

- If the dressing is not easily removed, soak with sterile saline or water until it is removed without difficulty.
- Due to the dressing's low pH, some patients may notice slight transient stinging. If stinging persists and can not be managed with an analgesic, remove dressing, cleanse area, and discontinue use of MEDIHONEY[®] dressing.
- During initial use of the dressing (depending on wound exudate levels, interstitial fluid, and edema surrounding the wound), the dressing's high osmolarity may contribute to increased exudate. This can be managed by adjusting the frequency of dressing change according to the level of exudate.
- During the healing process, due to autolytic debridement it is common for non-viable tissue to be removed from the wound resulting in an initial increase in wound size. Although an initial increase in size may be attributed to the normal removal of nonviable tissue, consult a healthcare professional if the wound continues to grow larger after the first few dressing changes.
- After removing the dressing, if some HCS Sheet material remains and is not easily removed, soak with sterile saline or water until it is removed without difficulty.
- Consult a healthcare professional if you see signs of infection, which can include increased redness, increased pain, increased wound drainage, increased skin irritation, and changes in wound color and/or odor.
- Do not use this dressing with any other wound care products, other than those listed in this package insert, without first consulting a healthcare professional.

DIRECTIONS FOR USE

- Prior to application of MEDIHONEY® Adhesive Hydrogel Sheet Dressing with *Leptospermum* Honey, cleanse the wound area as necessary.
- Use an appropriately sized MEDIHONEY[®] Adhesive Hydrogel Sheet Dressing with *Leptospermum* Honey. The outer edge of the dressing should extend at least ³/₄ inch beyond the wound edges.
- Open pouch and remove dressing. Remove bottom liners (marked "1") from dressing, exposing the wound contact surface of the dressing.
- Position dressing so that the center island completely covers the wound area, and apply. Smooth all edges and corners to ensure that dressing is properly adhered to skin.
- Remove top plastic liners (marked "2").
- If the wound exudate increases, placement of a barrier cream or ointment (compatible with adhesive dressings) around the periwound area can help to lengthen wear time of the dressing and prevent tissue maceration.

DRESSING CHANGE AND REMOVAL

- Dressing change frequency will depend on the condition of the patient as well as the level of wound exudate.
- Reapply when MEDIHONEY[®] Adhesive Hydrogel Sheet Dressing with *Leptospermum* Honey has reached its absorbent capacity or as directed by a wound care professional.
- Remove the dressing from the wound bed gently by pressing down on the skin with one hand and carefully lifting an edge of the dressing with your other hand. This edge can then be either stretched slightly or rolled gently to release the rest of the dressing.
- Upon removal, some residual hydrogel/colloidal material from the hydrogel dressing may be left behind on the wound bed. This material should be cleansed away as part of the normal cleansing process between dressing changes.
- Cleanse the wound bed prior to application of new dressing.

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

CAUTION: Do not use product if the immediate product packaging is damaged.

Store at room temperature: 10 – 25°C (50 – 77°F). Keep dry.

If further information or guidance is required, please contact Derma Sciences for assistance at:

1-800-445-7627 (USA)

1-800-387-5302 (Canada)

This article is covered by one or more patent applications or patents provided at www.dermasciences.com

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