STERILE

DuoDERM Signal®

A Tapered Edge CGF® Dressing

INSTRUCTIONS FOR USE

ConvaTec

- For Single Use

STERILE R - Gamma Sterilized

REF - Order Number

- Keep Dry

- Store at Room Temperature

- See Insert for Instructions for Use

LOT - Lot

- Expiration Date

PRODUCT DESCRIPTION

DuoDERM Signal®, A Tapered Edge CGF® (Controlled Gel Formulation) dressing, is an adhesive bordered (hydrocolloid) wound dressing. The dressing is tapered to be thinner at the edges than at the center so the incidences of rolling up during use are reduced. The hydrocolloids are contained within the dressing mass. The adhesive layer contains polymers which enhance the dressing's ability to contain wound exudate by forming a cohesive gel. An indicator line on the dressing helps to determine when to change the dressing. The wound fluid appears as a bubble moving toward the indicator line.

The dressing absorbs wound fluid and creates a moist environment which supports the body's healing process and aids in the removal of non-viable tissue from the wound (autolytic debridement), without damaging newly formed tissue.

DuoDERM Signal may be used as a primary dressing or as a secondary dressing. It may be used alone or in combination with other wound care products as directed by your healthcare professional.

DuoDERM Signal acts as a barrier to the wound against bacterial, viral and other external contamination. It minimizes the potential of exposure to nosocomial or infectious agents. The dressing has been shown in laboratory experiments (7 day testing period) to block the passage of bacteria and the Phi-X 174 virus (a validated surrogate for the Human Immunodeficiency Virus (HIV-1) and Hepatitis B Virus (HBV)) provided the dressing remains intact and there is no leakage. The use of this dressing neither guarantees nor warrantees against AIDS or Hepatitis B Virus transmission.

INDICATIONS

For Over - the - Counter use, DuoDERM Signal may be used for:

- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

Under the supervision of a healthcare professional, DuoDERM Signal may be used for wounds such as:

- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), diabetic ulcers and pressure ulcers/sores (partial & full thickness)
- surgical wounds (post-operative left to heal by secondary intention, donor sites, dermatological excisions)
- second degree burns
- traumatic wounds

CONTRAINDICATIONS

DuoDERM Signal should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.

PRECAUTIONS AND OBSERVATIONS

- Sterility is guaranteed unless pouch is damaged or opened prior to use. Single use only.
- This wound dressing should not be used with other wound care products without first consulting a healthcare professional.
- During the body's normal healing process, non-viable tissue (autolytic debridement) is removed from the wound, which could make the wound appear larger after the first few dressing changes. If the wound continues to get larger after the first few dressing changes, consult a healthcare professional.
- Should you observe irritation (reddening, inflammation), maceration (whitening of skin), hypergranulation (excess tissue formation) or sensitivity (allergic reaction) consult a healthcare professional.
- Frequent dressing changes on wounds with damaged or delicate skin surrounding the wound is not recommended. The wound should be inspected during dressing changes. Contact a healthcare professional if (1) signs of infection occur (increased pain, bleeding, wound drainage), (2) there is a change in wound color and/or odor, (3) the wound does not begin to show signs of healing and (4) any other unexpected symptoms occur.
- The dressing may be used on infected wounds only under the care of a healthcare professional.
- The use of this dressing neither guarantees nor warrantees against AIDS or Hepatitis B Virus transmission.

In addition, for leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), diabetic ulcers, pressure ulcers/sores, second degree burns, surgical wounds and traumatic wounds:

- Treatment of the wound types listed above should be under the supervision 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/sores).
- 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.

DIRECTIONS FOR USE

1. Wound Site Preparation and Cleansing
   Before using the dressing, clean the wound with an appropriate wound cleansing agent or normal saline and dry the surrounding skin.
2. Dressing Preparation and Application
   a. Choose a dressing size and shape to ensure that the dressing is 1 1/4 inches (3 cm) larger than the wound area in any one direction.
   b. Remove the release paper from the back being careful to minimize finger contact with the adhesive surface.
   c. Hold the dressing over the wound and line up the center of the dressing with the center of the wound. Place the dressing directly over the wound.
   d. For difficult to dress anatomical locations, such as heels or the sacrum, a supplementary securing device, such as tape, may be required.
   e. Discard any unused portion of the product after dressing the wound.
3. Dressing Change and Removal
   a. NOTE: The dressing should be inspected frequently for leakage, rolling up of the edges and/or whether any part of the bubble has reached the change indicator. If any of these occur, the dressing should be changed. As wound fluid is absorbed by the dressing, gel formation may be visible through the dressing.
   b. The dressing should be changed when: clinically indicated, when strike-through occurs, or up to a maximum of seven days. The wound should be cleansed at appropriate intervals.
   c. Press down gently on the skin and carefully lift one corner of the dressing until it is no longer adhered to the skin. Continue until all edges are free. Carefully lift away the dressing.

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

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

If further information or guidance is needed, please contact ConvaTec Professional Services.

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