Sterile

# DuoDERM® CGF®

*Control Gel Formula Dressing*

INSTRUCTIONS FOR USE

ConvaTec

## PRODUCT DESCRIPTION

DuoDERM® CGF® Control Gel Formula Dressing is an adhesive (hydrocolloid) wound contact dressing. 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.

The self adherent dressing absorbs wound fluid and provides a moist environment which supports the body's healing process and aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging new tissue.

DuoDerm CGF Control Gel Formula Dressing may be used alone or in combination with other wound care products as directed by your healthcare professional.

DuoDerm CGF Control Gel Formula Dressing acts as a barrier to the wound against bacterial, viral and other external contamination. The dressing has been shown in laboratory experiments to block the passage of bacteria and viruses to include the Human Immunodeficiency Virus (HIV-1) while the dressing remains intact without leakage. The use of this device neither guarantees nor warrantees against AIDS transmission.

## INDICATIONS

*For Over the Counter Use:*
DuoDerm CGF may be used for:

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

*Under the supervision of a healthcare professional, DuoDerm CGF 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 (partial & full thickness)
- surgical wounds (post-operative, donor sites, dermatological excisions)
- burns (first and second degree)
- traumatic wounds

* minimizes the potential of exposure to nosocomial or infectious agents

## CONTRAINDICATION

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

- Caution: Sterility is guaranteed unless package is damaged or opened prior to use. Single use only.
- Do not use this product in combination with other wound care products without first consulting a healthcare professional.
- During the body's normal healing process, unnecessary material 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 the 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 device neither guarantees nor warrantees against AIDS transmission.

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

- Treatment of the above wound types 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).
- 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. In the presence of a clinical anaerobic infection, occlusive therapy is not recommended.
- The control of blood glucose, as well as, appropriate supportive measures should be provided with diabetic foot ulcers.

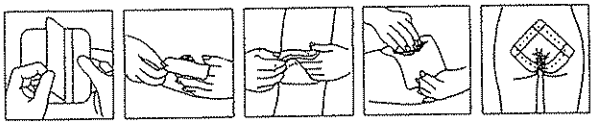
## DIRECTIONS FOR USE

Before using the dressing, clean the wound area with a wound cleansing agent or normal saline and dry the surrounding skin.

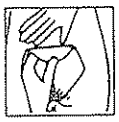
The size of the dressing to be applied to the wound should extend at least 1 1/4 inch (3.2 cm) beyond the edges of the wound.

1. Remove the release paper from the back of the dressing being careful to minimize finger contact with the adhesive surface.
2. Hold the dressing over the wound and line up the center of the dressing with the center of the wound.
3. Gently roll the dressing into place over the wound.
4. Mold the dressing into place with your hand.
5. Secure the edges of the dressing with medical or adhesive tape, if extra security is desired.
6. Discard any unused portion of the product after dressing the wound.

NOTE: The dressing should be inspected frequently for leakage and bunching/rolling up of edges. If any of these occur, the dressing should be changed. As wound fluid is absorbed by the dressing, gel formation may be visible on the outer surface of the dressing.



## REMOVAL OF THE DRESSING



1. Press down on the skin with one hand and carefully lift an edge of the dressing with your other hand. Gently roll off of the wound.

**Maximum recommended weartime is up to seven days.**

## STORAGE INSTRUCTIONS

Store at room temperature. Avoid refrigeration and exposure to high humidity.

If further information or guidance is needed, please contact ConvaTec Professional Services Department at 1-800-422-8811.

ConvaTec
Division of E.R. Squibb & Sons, L.L.C.
Princeton, NJ 08543
1-800-422-8811

Distribué par:
ConvaTec
Une Division de Bristol-Myers Squibb Canada
Montréal, Québec, Canada
1-800-465-6302

ConvaTec
A Division of Bristol-Myers Squibb Australia Pty Ltd
Level 1, 352 Wellington Road
MULGRAVE VIC 3170
(PO Box 63, Mulgrave)
Free Call 1800 335 276
61 3 8562 1300

ConvaTec
A Division of Bristol-Myers Squibb Pharmaceuticals Pty Ltd
Worldwide Tower
Level 8, 8-10 Whitaker Place
(P.O. Box 62663 Kalmia Street )
Auckland, NEW ZEALAND
Free Call 0800 44 1763

ConvaTec North Pacific
C/O A Bristol-Myers Squibb Company (HK) Ltd.
Unit D, 16/F., Manulife Tower
169 Electric Road
North Point
Hong Kong
Tel: (852) 2510 6500 Fax: (852) 2516 9449

ConvaTec
c/o Bristol-Myers Squibb (HK) Ltd.
Room 3004, 30th Floor
New York Life Tower
Windsor House
311 Gloucester Road
Causeway Bay
Hong Kong
Phone: (852) 25169182

Made in USA