



Title	Instructions For Use Barrier Cream	
Revision	C	
Technical documentation Number	LFD-PKG-000296	

1.0 PRODUCT DESCRIPTION

Barrier Cream is a white concentrated cream that provides protection to skin from body fluids. It protects dry, chafed, red, or irritated skin by moisturising the skin and providing a long lasting barrier. Use of this cream allows adhesive products to stick to the skin.

2.0 INTENDED PURPOSE

Barrier Cream protects at-risk skin areas from damage and irritation associated with incontinence. Barrier Cream maintains and preserves skin from damage associated with chronic incontinence. It moisturizes and protects severely dry skin. The cream will not reduce adhesion of medical tapes or adhesive dressings.

2.1 INTENDED POPULATION

The Barrier Cream may be used on adults, children and infants over 12 weeks old.

2.2 INTENDED USER

Intended for use by health professionals and caregivers and may be used in a hospital, community and home setting.

3.0 INDICATIONS

Barrier Cream is used for prevention of incontinence-associated dermatitis, prevention of skin breakdown linked to incontinence, prevention of skin breakdown linked to bodily fluids, and moisturising of severely dry skin.

4.0 CONTRAINDICATIONS/SAFETY INFORMATION

Barrier Cream should not be used on infected skin. Barrier Cream should not be used where there is known allergic sensitivity to the ingredients.

5.0 WARNINGS

Barrier Cream may increase the adherence of some adhesive products. If skin condition worsens or does not improve within 7 days, consult a physician. Keep out of reach of children. In case of ingestion, seek medical help. For external use only. Avoid contact with eyes.

6.0 INFORMATION FOR USE

Gently cleanse skin area as required. Spread Barrier Cream thinly to cover entire affected area. Repeat as necessary. If the feel is oily, too much has been applied.

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Ingredients

Purified Water, Ethylhexyl Isononanoate, Disiloxane, Polyisobutylene, VP Eicosene Copolymer, Hydroxyethyl Acrylate / Sodium Acryloyl Dimethyl Taurate Copolymer, Butylene Glycol, Oleth-3 Phosphate, Phenoxyethanol, Hydrogenated Styrene/Isoprene Copolymer, Allantoin, Carbomer, Triethanolamine, Methylparaben, Propylparaben, Disodium EDTA.

*Skin moisturising ingredients ethylhexyl and butylene Glycol constitutes 8% - 12% of total ingredients respectively, also Barrier protectant ingredients Polyisobuytelene, VP & copolymer constitutes 1% -10% of total ingredients respectively.

There are no known other components (or associated interactions) in the final product that would require further evaluation. All compounds are considered stable & non-reactive. No compounds in the formulation are expected to cross react resulting in a potentially hazardous compound being formed (There are no known oxidizing compounds or reactive compounds (i.e. reducers etc) in the formulation).

7.0 CLINICAL BENEFITS/ SPECIAL NOTES

The Barrier Cream forms a durable barrier that works as a protective shield between the skin and bodily wastes and fluids. The product is designed to assist barrier resistance against irritation from body fluids.

Barrier Cream is used for the prevention of moisture associated skin damage, and the treatment of moisture associated skin damage.

8.0 STORAGE




Store dressings away from direct sunlight at ambient temperature and humidity.

9.0 DISPOSAL

Product - This must be disposed of in compliance with anti-pollution and other laws of the country concerned. Contact your local service providers for further information.

Packaging - Disposal must be made in accordance with local waste management regulations. Outer packaging may be recycled. Contact your local service providers for further information.

10.0 SYMBOLS ON LABELLING

WARNINGS	
	Do not use if the pouch is damaged or opened.
	Medical Device
STORAGE	
	

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11.0 PRESENTATION

Cat. No.	Size	No. / Box
BC2801	Barrier Cream 28g Tube	1
BC2812	Barrier Cream 28g Tube	12
BC9001	Barrier Cream 90g Tube	1
BC9012	Barrier Cream 90g Tube	12
BC0220	Barrier Cream 2g Sachet	20

12.0 COMPLAINTS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For complaints, questions or comments, contact Avery Dennison Medical Customer Support at phone +353 43 3349586.



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Made in Ireland



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13.0 REVISION HISTORY

Revision	Change History	Date	Originator
A	Initial upload into MasterControl	01/10/2021	I. Mats
B	Update of CE number to 2797. Addition of infocard number. Revision of intended population to include “infants over 12 weeks”. Revision of intended purpose, indications and clinical benefit.	06/10/2021	D. Casey
C	Section 6 Added last paragraph * to Ingredient section. Section 7 add Barrier Cream is used for the prevention of moisture associated skin damage, and the treatment of moisture associated skin damage.	29 Apr 2022	Emmett McArdle

14.0 APPROVAL

Review and Approval	
<u>Name and Title</u>	<u>Signature and Date</u>
Lisa Bartakovics Sr. Global Director RA & Quality	Approvals are captured via MasterControl
Emmett McArdle R&D Manager	Approvals are captured via MasterControl
Paul Saunders Sr. Global Marketing Manager	Approvals are captured via MasterControl
Elaine Minagh Regulatory Affairs Manager	Approvals are captured via MasterControl

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