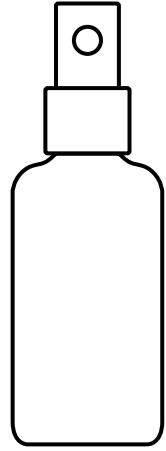


Barrier Film Spray

28 ml
Swab



LFD-PKG-000261 Rev A

en

1.0 PRODUCT DESCRIPTION

Barrier Film is a polymeric solution which forms a uniform film when applied to the skin. The product is dispersed in a non-stinging solvent, which dries rapidly. The film is colourless, transparent, and possesses good oxygen and moisture vapour permeability. Barrier Film helps to protect intact or damaged skin from irritation caused by urine and/or fecal incontinence, digestive juices and wound drainage. Barrier Film is a multiple use device that is intended for single patient use.

2.0 INTENDED PURPOSE

Barrier Film is a liquid intended for use as a film-forming product that upon application to intact or damaged skin forms a long lasting waterproof barrier, which acts as a protective interface between the skin and bodily wastes and fluids. It is intended as a primary barrier against irritation from bodily fluids and can be used on adults and children.

2.1 INTENDED POPULATION

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

2.2 INTENDED USERS

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

3.0 INDICATIONS

The products are indicated for protecting intact or damaged skin from body fluids in the areas of:

- Incontinence skin care
- Peri-stomal skin protection
- Peri-wound skin protection

4.0 CONTRAINDICATIONS

Barrier Film is not to be used as the only covering in situations that require dressing protection from bacterial contamination / penetration, e.g. intravenous therapy catheter sites and full or partial thickness wounds. Barrier film is not to be used on infected skin.

5.0 WARNING

Barrier Film, in liquid form, is flammable: use in a well ventilated area. Avoid using around flames and sources of ignition. Keep out of reach of children.

Do not use if pack is damaged or open.

6.0 INFORMATION FOR USE

- Visually inspect spray bottle for damage prior to opening.
- Skin should be clean and dry prior to application of Barrier Film.
- Hold spray nozzle 100 to 150 mm (4 - 6 inches) from skin and apply a smooth, uniform coating of film over entire area of concern, while moving spray in a sweeping motion.
- If an area is missed, reapply to that area only after first application of Barrier Film has dried (approximately 30 seconds).
- If Barrier Film is applied to an area with skin folds or other skin-to-skin contact, make sure that skin-contact areas are separated to allow the film to thoroughly dry before returning to normal position.
- When used under adhesive tapes, dressings, or devices: Allow Barrier Film to thoroughly dry before covering with dressing or adhesive products.
- Reapplication of Barrier Film is necessary each time dressing and/or adhesive products are changed: the barrier film is removed by the adhesive.
- When used as a protectant against body fluids, feces, or urine etc., and no adhesive products are applied to skin:
- Reapplication of Barrier Film is recommended every 24-72 hours, depending on frequency of cleaning.
- In extreme cases (e.g. constant diarrhoeal stooling) with very frequent cleansing, more frequent applications may be necessary (i.e. every 12-24 hours).
- If desired, the film can be removed by using most medical adhesive removers as directed. Clean and dry the involved area and reapply Barrier Film.
- Replace cap over spray nozzle when not in use.

Ingredients

- Disiloxane, Acrylate Copolymer

7.0 CLINICAL BENEFITS /SPECIAL NOTES

Barrier films offer protection to the skin against subsequent moisture contact. The Barrier film forms a thin layer, repelling moisture and potential irritants, thus protecting the skin.

Caution

- Should redness or any other signs of irritation appear, or if redness or signs of irritation persist, cease the use of Barrier Film and consult a physician.
- Use of other barrier products, ointments, creams or lotions may significantly reduce the effectiveness of Barrier Film.
- Contents of the spray bottle are sterile until first use.

8.0 STORAGE

Barrier film should be stored in the original container in a dry place at ambient temperature and humidity, and away from direct heat or sunlight. Product should be discarded 28 days after opening.

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	
	Flammable
	Do not use if the pouch is damaged or opened
	Medical Device
	Attention. See instruction for use
	Single patient multiple use
STORAGE	
	Keep away from sunlight
	Keep dry
STERILE	
	Method of sterilization: Gamma
	Do not re-use
	Do not re-sterilize
OTHER	
	Unique Device Identifier

11.0 PRESENTATION

CAT. NO.	SIZE	NO./BOX
BF2801	28ml Spray Bottle	1
BF2812	28ml Spray Bottle	12

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.

Manufactured by:
Avery Dennison Medical Ltd.
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Longford, N39 DX73, Ireland
phone +353 43 3349586
fax +353 43 3349566

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applications.

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Ig1

1.0 LOREM IPSUM

Mollis nunc sed id semper risus in hendrerit gravida. Ut faucibus pulvinar elementum integer enim neque volutpat ac tincidunt. Netus et malesuada fames ac turpis egestas integer eget. Purus sit amet luctus venenatis lectus magna fringilla urna porttitor. Ultricies mi quis hendrerit dolor magna eget. Ullamcorper

senectus et netus et. Maecenas sed enim ut sem viverra aliquet eget sit. Sit amet porttitor eget dolor morbi non arcu. Purus in massa tempor nec feugiat nisl pretium fusce.

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8.0 MAGNIS

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9.0 TINCIDUNT

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10.0 ORNARE SUSPENDISSE

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11.0 GRAVIDA DICTUM

CAT. NO.	SIZE	NO./BOX
BF2801	28ml Spray Bottle	1
BF2812	28ml Spray Bottle	12

12.0 COMMODO ODIO

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10.0 ORNARE SUSPENDISSE

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	Rhoncus est pelle
STERILE	
	Pellentesque habitant morbi tristique
	Purus ut faucibus
	Pulvinar elementum integer
OTHER	
	Alblivando Esprensi dolronomic

11.0 GRAVIDA DICTUM

CAT. NO.	SIZE	NO./BOX
BF2801	28ml Spray Bottle	1
BF2812	28ml Spray Bottle	12

12.0 COMMODO ODIO

Urna cursus eget nunc scelerisque viverra mauris in aliquam. Ipsum dolor sit amet consectetur adipiscing elit pellentesque. Pellentesque habitant morbi tristique senectus et netus et malesuada. Vestibulum lectus mauris ultrices eros in cursus turpis massa tincidunt.

Ut faucibus pulvinar elementum integer enim neque volutpat ac tincidunt. Netus et malesuada fames ac turpis egestas integer eget.

Manufactured by:
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lg3

1.0 LOREM IPSUM

Mollis nunc sed id semper risus in hendrerit gravida. Ut faucibus pulvinar elementum integer enim neque volutpat ac tincidunt. Netus et malesuada fames ac turpis egestas integer eget. Purus sit amet luctus venenatis lectus magna fringilla urna porttitor. Ultricies mi quis hendrerit dolor magna eget. Ullamcorper velit sed ullamcorper morbi tincidunt ornare. Egestas fringilla phasellus faucibus scelerisque eleifend donec pretium vulputate sapien. Donec adipiscing tristique risus nec feugiat in fermentum posuere. Dui vivamus arcu felis bibendum.

2.0 DOLOR SIT AMET

Quam quisque id diam vel quam elementum. Rhoncus est pellentesque elit ullamcorper. Etiam sit amet nisl purus in. Netus et malesuada fames ac turpis egestas maecenas pharetra. Fusce id velit ut tortor pretium viverra. Purus ut faucibus pulvinar elementum integer enim neque volutpat. Interdum velit laoreet id donec ultrices. Mauris ultrices eros in cursus.

2.1 MOLLIS NUNC SED

Mauris commodo quis imperdiet massa tincidunt nunc pulvinar. Tellus elementum sagittis vitae et. Condimentum id venenatis a condimentum vitae sapien pellentesque habitant.

2.2 BLANDIT CURSUS RISUS

Volutpat lacus laoreet non curabitur. Vestibulum rhoncus est pellentesque elit ullamcorper dignissim cras tincidunt lobortis. Fermentum dui faucibus in ornare quam viverra orci.

3.0 POSUERE

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- Interdum velit euismod in pellentesque
- Magna fermentum iaculis eu non diam phasellus
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4.0 ULLAMCORPER

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5.0 TURPIS CURSUS

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Vestibulum lectus mauris ultrices eros in cursus turpis massa tincidunt.

6.0 QUAM QUISQUE

• Mollis nunc sed id semper risus in hendrerit gravida.

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- Netus et malesuada fames ac turpis egestas integer eget. Purus sit amet luctus venenatis lectus magna fringilla urna porttitor. Ultricies mi quis hendrerit dolor magna eget.
- Ullamcorper velit sed ullamcorper morbi tincidunt ornare. Egestas fringilla phasellus faucibus scelerisque eleifend donec pretium vulputate sapien.
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- Vestibulum lectus mauris ultrices eros in cursus turpis massa tincidunt.
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Facilis

- Disiloxane, Acrylate Copolymer

7.0 DIAM VEL QUAM /VENENATIS A CONDE

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2. Purus sit amet luctus venenatis lectus magna fringilla urna porttitor. Justo eget magna fermentum iaculis eu non diam.

8.0 MAGNIS

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9.0 TINCIDUNT

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2.0 DOLOR SIT AMET

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2.1 MOLLIS NUNC SED

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10.0 ORNARE SUSPENDISSE

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	Rhoncus est pelle
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	Pellentesque habitant morbi tristique
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11.0 GRAVIDA DICTUM

CAT. NO.	SIZE	NO./BOX
BF2801	28ml Spray Bottle	1
BF2812	28ml Spray Bottle	12

12.0 COMMODO ODIO

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Ig4

1.0 LOREM IPSUM

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2.0 DOLOR SIT AMET

Quam quisque id diam vel quam elementum. Rhoncus est pellentesque elit ullamcorper. Etiam sit amet nisl purus in. Netus et malesuada fames ac turpis egestas maecenas pharetra. Fusce id velit ut tortor pretium viverra. Purus ut faucibus pulvinar elementum integer enim neque volutpat. Interdum velit laoreet id donec ultrices. Mauris ultrices eros in cursus.

2.1 MOLLIS NUNC SED

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condimentum vitae sapien pellentesque habitant.

2.2 BLANDIT CURSUS RISUS

Volutpat lacus laoreet non curabitur. Vestibulum rhoncus est pellentesque elit ullamcorper dignissim cras tincidunt lobortis. Fermentum dui faucibus in ornare quam viverra orci.

3.0 POSUERE

Aliquam nulla facilisi cras fermentum odio eu. Quis commodo odio aenean sed adipiscing diam donec adipiscing tristique:

- Interdum velit euismod in pellentesque
- Magna fermentum iaculis eu non diam phasellus
- Tellus elementum sagittis vitae et

4.0 ULLAMCORPER

Dignissim enim sit amet venenatis urna cursus eget nunc scelerisque. Non arcu risus quis varius quam. Nunc lobortis mattis aliquam faucibus purus in. Gravida quis blandit turpis cursus in hac habitasse platea dictumst. Sit amet volutpat consequat mauris nunc congue nisi vitae. Et magnis dis parturient montes nascetur ridiculus mus. Ligula ullamcorper malesuada proin libero. Mattis enim ut tellus elementum sagittis vitae et leo duis.

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6.0 QUAM QUISQUE

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