

SORBADERM[®]

Barrier Cream



Size	No./Box	Ref. No.
Barrier Cream 2g Sachet	20	3026
Barrier Cream 28g Tube	1	3027
Barrier Cream 92g Tube	1	3028



Medical Device



Do not use if pack is damaged



Unique Device Identifier



Single Patient Multiple Use



Made in Ireland



Attention. See instruction for use



Products packaging can be recycled



Keep away from sunlight



Consult instructions for use or consult electronic instructions for use



Keep dry



The product has not been sterilised

**UK
CA**
0086

UK Responsible Person:

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Sorbaderm® Barrier Cream

INSTRUCTIONS FOR USE

1. 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. Barrier Cream is a multiple use device that is intended for single patient use.

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

2.2 Intended User

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

3. 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. 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. 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. 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.

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 Polyisobutylene, 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. Clinical Benefits

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 treatment of moisture-associated skin damage.

8. Storage

Store dressings away from direct sunlight at ambient temperature and humidity. Product should be discarded 28 days after opening.

9. 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. 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.