

Product Description

3M™ Cavilon™ Advanced Skin Protectant is a polymeric-cyanoacrylate solution intended for the protection of intact or damaged skin. Upon application to skin, the liquid dries rapidly to form a primary long-lasting waterproof, highly durable film barrier. It is elastomeric, adhering to the contours of the skin and providing a uniform film. The film is transparent and possesses good oxygen and moisture vapor permeability.

The polymer-cyanoacrylate is dispersed in a non-stinging solvent. The film is colorless, non-cytotoxic and has a low dermatitis potential. The film adheres to dry, moist or wet skin surfaces and remains intact during conditions of continuous or repeated exposure to moisture or caustic irritants. It will wear off the skin and does not require removal.

Ingredients: Hexamethyldisiloxane, Acrylic Tetrapolymer, 2-Octyl Cyanoacrylate

Indications for Use

Cavilon Advanced Skin Protectant forms a film barrier intended to protect intact or damaged skin. It is effective in conditions where skin is frequently or continuously exposed to moisture and caustic irritants such as feces, digestive fluids, wound drainage and urine. Cavilon Advanced Skin Protectant also can be used in areas exposed to friction and shear from bedding, clothing, shoes or any other material that would rub against the skin.

Contraindications

Cavilon Advanced Skin Protectant is NOT to be used:

- as a wound dressing for full thickness wounds
- in or around the eyes

Warnings

1. **DANGER! EXTREMELY FLAMMABLE!**
2. Cavilon Advanced Skin Protectant is extremely flammable until it has completely dried on the skin.
3. The product should only be applied when no ignition sources or heat-producing devices are in use.
4. Avoid using the product around flames.
5. Use the product only in well ventilated areas.
6. Avoid use on individuals who are allergic to any of the ingredients.
7. The product is individually packaged for single use only. Reuse could result in increased risk of infection, or inadequate product performance.
8. The product is not intended for applications requiring sterile product (e.g. infusion catheter site protection and care, or surgical site protection).
9. Keep out of the reach of children.

Caution: Federal Law (U.S.A.) restricts the device to sale by or on the order of a health care professional.

Precautions

- Skin absorption and the effectiveness of topical medications (including: antimicrobials, antifungals, and analgesics) may be reduced or prevented by the presence of the Cavilon Advanced Skin Protectant.
- Use of other barrier products, ointments, creams or lotions may significantly reduce the effectiveness of the product.
- The product can increase the adhesion of some adhesive products (e.g. tape), particularly in the first few days of use. When removing an adhesive product, it is important to exercise care and follow the Directions for Use (Step 10, below)

Directions for Use

- 1) Cleanse skin before applying Cavilon Advanced Skin Protectant. Gently dry areas of intact skin as needed. If areas of erosion (denudement) are present, excess serous or sero-sanguinous drainage may be blotted with a gauze pad if necessary.
- 2) Open package and grasp applicator. See Figure 1. Place thumb at the end of the lever. Aim the sponge end of the applicator **downward** and firmly depress the lever to break the internal ampule. A snapping or popping noise will be noted as the ampule breaks. It is not necessary to continue to press the lever.
- 3) Keep the applicator pointed in a downward position for approximately 10 seconds to allow fluid to flow into the foam sponge; continued pressure on the lever is not required. Note-fluid will not completely saturate the sponge to the edges.
- 4) Using an even, sweeping motion (Figure 2), gently wipe the foam sponge across the skin with minimal overlap. Firm pressure and/or downward pressure on the lever or the applicator is *not* needed and may result in excessive wetness or pooling of fluid. Continue application until the entire area of concern has been covered. The applicator may be used in any direction.
Apply the product to *all* skin that is exposed to stool and/or urine, or irritating body fluid. Allow the area to dry for at least 30 seconds. (Figure 3)
If an area is missed, wait until the fluid has dried completely before applying additional product.
- 5) If Cavilon Advanced Skin Protectant is applied within a skin fold or other area of skin-to-skin contact, make sure that the skin surfaces are separated to allow the fluid to dry completely (*at least 30 seconds*) before allowing skin to return to the normal position.
- 6) **When used under adhesive tapes, dressings, or devices, allow the product to dry for approximately 1 minute before covering with adhesive products.** Refer to Precaution Statement # 3.
- 7) Cleanse affected area as needed. Cavilon Advanced Skin Protectant is waterproof and is not removed by cleansing.
- 8) Reapply two to three times per week. More frequent application may result in buildup of the product.
- 9) The film will wear off the skin and does not require removal. If removal is desired, the film should be removed with an adhesive remover containing hexamethyldisiloxane (HMDS).
- 10) Use an adhesive remover containing HMDS to remove an adhesive product that has been placed over the film. This is especially important for patients with fragile skin.



Figure 1

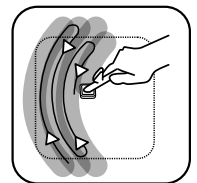


Figure 2



Figure 3

Storage/ Shelf Life/Disposal

For best results, the product should be stored in a cool and dry environment. Avoid excessive heat.

For shelf life, refer to the expiration date on each package.

Refer to facility policy for disposal.

How Supplied

Applicators are individually packaged for single patient, one-time use only. The fluid within the ampule is non-sterile. The applicator is sterile if package is intact. Do not use the product if the package is damaged or opened.

For further information, please contact your local 3M representative or contact us at 3M.com

Explanation of Symbols

- Not Made With Natural Rubber Latex
- Caution, see instructions for use
- Do not use if package is damaged or open
- Do not reuse
- Use by date
- LOT Batch code
- Manufacturer
- STERILE EO Sterilized using ethylene oxide
- DANGER! EXTREMELY FLAMMABLE!**
- Date of manufacture

Made in U.S.A. by

3M Health Care

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