

LIQUID SKIN PROTECTANT

Liquid barrier film for the protection of the skin

DESCRIPTION

TearRepair™ Liquid Skin Protectant is a non-cytotoxic, methylidene malonate based, rapid-drying liquid barrier film for the protection of the skin. It is applied as a liquid and dries within minutes, adhering to the contours of the skin to form a transparent flexible film. TearRepair will wear off, naturally. The product is provided sterile.

INDICATIONS FOR USE

TearRepair is used in areas exposed to mechanical forces such as friction and shear from bedding, clothing, shoes, or any material that may damage the skin. TearRepair can also be used to protect skin exposed to irritation from moisture such as urine, feces, digestive juices, perspiration, and wound drainage. TearRepair can also help protect the skin against irritation caused by adhesive products.

CONTRAINDICATIONS

Do not apply as a wound dressing for full thickness wounds or in or around the eyes. Do not apply directly to deep, open or bleeding wounds. Do not apply to chronic wounds (persistent or unhealing wounds). Do not apply to second- or third-degree burns. Do not apply to infected areas.

DIRECTIONS (Please use under the guidance of a healthcare professional.)

PREPARE APPLICATION SITE:

Clean and dry the skin thoroughly before applying. Ensure that all traces of moisturizers, lotions, lotion soaps or lanolin are removed from the application site.

TO APPLY:

1. Remove the applicator from the foil pouch.
2. Using gloved hands, hold the applicator with the tip pointing upwards and away from the patient. Squeeze the center of the applicator tube to rupture the glass ampoule within. If needed, apply pressure using both hands with one thumb atop the other (Figure 1). A snapping or popping noise will be noted as the ampoule breaks.
3. Invert the applicator so that its tip points downwards (Figure 2).
4. With the applicator positioned close to and above the treatment site, squeeze the applicator tube a few times to facilitate the flow of the blue liquid adhesive through the visible filter and tip. This process may take several seconds. Once the blue adhesive appears on the tip, the pressure applied to the tube may be released. Continue gently pumping the tube while applying to the affected area to facilitate the flow of product from the device.
5. As the liquid expels from the device, use a gentle painting action to evenly spread the product in a thin layer over the treatment area. Ensure that the desired area is completely covered and extends at least 1 inch (2.5 cm) beyond the affected region. Avoid accumulation or dripping of product at the outside borders of the application area.
6. Allow up to 2 minutes for the product to dry. Some people may feel a temporary warming sensation as the product dries.

Figure 1

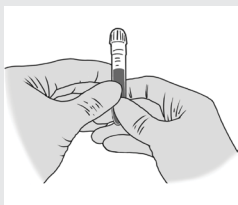
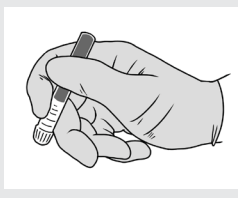


Figure 2



ADDITIONAL APPLICATION INFORMATION

- If TearRepair 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 before allowing skin to return to the normal position.
- Ensure that TearRepair has dried completely before covering with clothing, adhesive products, dressings, or applying incontinence products.
- Cleanse the affected area as needed. TearRepair is not removed by cleansing.
- Do not apply excessively in a thick layer as the adhesive may not be as effective and there may be an increased intensity of a warming sensation as the product dries.
- If an area is missed, wait until the fluid has dried completely before applying additional product.

REMOVAL

- The film will wear off the skin naturally within approximately 3 days and does not require removal.
- Excess TearRepair can be removed before it dries by wiping with a clean tissue. Once dry, unwanted TearRepair can be softened with petroleum jelly and removed.

WARNINGS AND PRECAUTIONS

- If TearRepair enters the eye, immediately flush with lukewarm water. Do not rub or try to separate the eyelids. Seek medical attention.
- The product is individually packaged and should be disposed of after use. Some treatment sites may require use of more than one unit.
- If irritation or prolonged pain develops (redness, inflammation, prolonged heat, and change in skin color) immediately discontinue product use. If irritation persists, seek medical attention.
- Polymerization of TearRepair may be accelerated by the presence of water or fluids containing alcohol. TearRepair should not be applied to wet or moist skin.
- Do not use under drug delivery patches.
- Avoid contact with mucous membranes such as the eyes and mouth.
- TearRepair should dry before coming into contact with other skin or materials, to avoid unintentional adherence.
- TearRepair may produce a temporary warming sensation as applied in a thin layer. Excessive application in a thick layer will cause an increase in the intensity of warming.
- Use of other barrier products, ointments, creams, or lotions may significantly reduce the effectiveness of the product.
- Keep out of reach of children.
- If TearRepair accidentally contacts an open wound, flush with warm water. Removal is not necessary.
- If the skin or other materials become stuck to the area, gently roll apart to separate. If unable to separate easily, seek medical attention.

OTHER INFORMATION

- Store in a cool, dry place. Avoid high humidity and excessive heat.
- For shelf life, refer to the expiration date on the packaging.
- Dispose of in accordance with local guidance.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed healthcare practitioner).

Product Description	Product SKU	Product Reference	Units/Box
TearRepair Skin Protectant 1g (5 ea.)	TSOM100TR	TR100	5



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