

## **Skin Protective Barrier Spray**

### **Instructions for use**

#### **Product description**

Skin protective barrier spray is a versatile, alcohol-free, liquid film forming skin protectant for minor wound and intact skin. The product may be used on adults, children, and full-term infants from one month with normal skin.

#### **Intended purpose**

Skin protective barrier spray is intended to act as a protective interface between minor wounds or intact skin and body's wastes, fluids, adhesive dressings, drainage tubes, catheters, and ostomy products to protect the wound from bacteria and dust, provide protection from adhesive trauma, prevent maceration of periwound skin, promote atraumatic dressing removal and help protect areas at risk of friction damage.

#### **Intended user**

The product may be used by or under the supervision of a healthcare professional, or used by a household consumer.

#### **Indications**

Skin protective barrier spray forms a waterproof, flexible, transparent, and breathable protective film on the wound surface and acts as a physical barrier to protect the wound from bacteria and dust.

Skin protective barrier spray can also be used on intact skin to help prevent medical adhesive-related skin injury (MARS) and moisture-associated skin damage (MASD) because it forms a barrier between the skin and body's wastes, fluids, adhesive dressing, drainage tubes, external catheters and around ostomy site, protecting body parts that may be irritated by friction damage from external surfaces.

**Contraindication**

- Do not apply to infected wound or skin.
- Do not use on patients with a known allergy to any of the ingredients.
- Do not use on deep puncture wounds. Use only on minor wounds.

**Adverse reaction**

The human bodies are well tolerate to form dressing products, however, after combined the available clinical data and post-marketing data of competitive device and benchmark devices, the following situations are identified and they are very rare:

- Potential risk of adverse reaction (redness, blisters, burning, itching)
- Flammability

**Instructions for use**

- 1) Wash hands and ensure that the affected area is clean and dry before application.
- 2) Spray a thin film on the affected area from a distance of 10-15cm. The film will dry in approximately 30 seconds. If you miss an area that you intended to cover, wait until the original area of application has dried before reapplication on missed area.
- 3) For maximum protection, an optional second coating may be applied.
- 4) The film should be dry before covering the affected area with dressing or other adhesive product. When used under adhesive products, reapplication is necessary each time when you change the adhesive products as the protective film can be removed by the adhesive.
- 5) If it 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 coating to thoroughly dry before returning to normal position.
- 6) The product can be reused within 24h according to the cleaning frequencies. In extreme cases with more frequent cleansing, more frequent applications may be necessary (i.e. every 12 – 24 hours).
- 7) Removal of the protective film is not necessary before reapplication. However, if removal is desired, the film can be removed by using most medical adhesive removers. Clean and dry the area before reapplication.
- 8) When it is no longer used, cover the nozzle cover again to prevent accidents.

### Warnings & Precautions

- For external use only.
- Avoid contact with eyes. In the case of accidental contact, flush eyes well with water.
- Keep out of the reach of children.
- Store in a cool, ventilated and dry warehouse, away from flame, heat and sun exposure.
- Should redness or other signs of irritation appear, discontinue use.
- If signs of an allergic reaction are detected, discontinue use of the product and seek advice from a qualified healthcare professional.
- Do not use it near fire or flame, heat, sparks and sources of static discharge or any ignition sources and heat-producing devices.

### Storage and transport conditions

Storage conditions: Store in a cool, ventilated and dry warehouse, away from flame, heat and sun exposure.

Transport conditions: Should be to prevent the weight, sun and rain and rain dripping.

### Disposal

Disposal should be handled according to local environment procedures.

### Other informations

If have any serious incident that has occurred in relation to the device, please reported to the manufacturer and the competent authority.



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### The meaning of the symbols used:

Symbol		EU REP			LOT
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<b>Title</b>	Manufacturer	Authorized representative in the European Union	Date of manufacture	Use-by date	Batch code
<b>Symbol</b>					
<b>Title</b>	Catalogue number	Importer	Distributor	Country of manufacture	Sterilized using irradiation
<b>Symbol</b>					
<b>Title</b>	Do not re-sterilize	Do not use if package is damaged	Single sterile barrier system	Keep away from sunlight	Keep dry
<b>Symbol</b>					
<b>Title</b>	Do not re-use	Consult instructions for use	Caution	Medical device	Unique device identifier
<b>Symbol</b>					
<b>Title</b>	CE marking	This way up	Danger, highly flammable liquid and vapor		

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