Mölnlycke®

Normlgel® Ag

Silver Antimicrobial Wound Gel



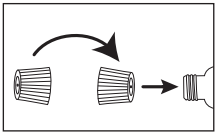
Mölnlycke®

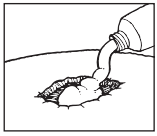
Manufactured in the U.K. and Distributed by:
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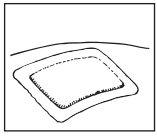
Advanced Medical Solutions Limited
Premier Park, 33 Road One
Winsford Industrial Estate
Winsford, Cheshire, CW7 3RT, U.K.

Toll free number: USA 1-800-882-4582

℞ only Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician [or properly licensed practitioner].







Normlgel® Ag

Silver Antimicrobial Wound Gel

Product Description

Normlgel® Ag is an opaque, amorphous hydrogel containing a high (>80%) water content and water soluble polymer chains. This formulation increases the moisture within the wound through water donation which makes the gel effective in assisting the debridement and desloughing process in dry necrotic wounds, whilst maintaining a moist wound environment for optimal wound healing.

Normlgel® Ag contains an antimicrobial silver compound (silver carbonate) that is an effective barrier to bacterial penetration by inhibiting the growth of broad spectrum of microorganisms which come into contact with the gel.

The nominal silver content is 0.11% [1100µg/gram]

In-vitro testing

In-vitro testing has shown that Normlgel® Ag is effective against the following broad spectrum of microorganisms; *Staphylococcus aureus*, including MRSA, *Staphylococcus epidermidis*, including MRSE, *Streptococcus pyogenes*, *Pseudomonas aeruginosa*, *Escherichia coli* and fungi such as *Candida albicans* and *Aspergillus brasiliensis* when they come into contact with the gel. The clinical implications of the *in-vitro* findings are unknown.

Indications

Normlgel® Ag is indicated under the medical supervision of a healthcare professional for the management of dry to moderate exuding partial and full thickness wounds such as:

- Pressure ulcers
- Leg ulcers
- Diabetic ulcers
- Graft and donor sites
- Post-operative surgical wounds
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- First and second degree burns
- Abrasions and lacerations

Contraindications

Normlgel® Ag should not be used on patients with a known sensitivity to silver or Propylene glycol

Precautions

- Frequent or prolonged use of this preparation may result in permanent discoloration of skin and mucous membranes.
- Discard the tube and any remaining gel 28 days after opening.
- For Single Patient Use Only.
- For external use only.
- Do not sterilise
- Do not use if individual tube is damaged or opened.
- Store at room temperature (15-25ºC/59-77ºF)

Directions for Use

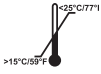
1. Cleanse or gently flush the wound with normal saline solution or an appropriate wound cleanser.
2. Apply Normlgel® Ag onto the wound bed (approximately 0.2 inches thick).
3. Ensure the Normlgel® Ag does not cover healthy skin.
4. Cover the gel with an appropriate moisture retentive secondary dressing (such as Mepilex Border Flex or Mepilex Border Flex Lite). The choice depends on the exudate level.

Dressing Change and Removal

1. Normlgel® Ag may be left in place for up to 3 days. Dressing changes may be required more frequently dependent upon wound conditions and the levels of exudate.
2. Carefully remove the secondary dressing. Cleanse or gently flush the wound with normal saline solution to remove necrotic debris.

Normlgel® is a registered trademark of Mölnlycke Health Care AB

Issued 2023-07

USA SDO Designated Number (5-134): ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied- Part 1: General Requirements.		
Symbol	The Title of the Symbol and Its Reference Number	The Meaning or Explanatory Text for the Symbol
	5.1.1 MANUFACTURER	Indicates the medical device manufacturer, as identified in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	5.1.4 USE-BY DATE	Indicates the date after which the medical device is not to be used.
	5.1.5 BATCH CODE	Indicates the manufacturers batch code so that the batch or lot can be identified.
	5.1.6 CATALOGUE NUMBER	Indicates the manufacturer's catalogue code so that the medical device can be identified.
	5.2.8 DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.3.4 KEEP DRY	Indicates a medical device that needs to be protected from moisture.
	5.3.7 LIMIT OF TEMPERATURE	Indicates the temperature limits to which the medical device can be safely exposed.
	5.4.2 DO NOT RE-USE	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.3 CONSULT INSTRUCTIONS FOR USE	Indicates the need for the user to consult the instructions for use.
	5.4.4 CAUTION	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.