

KERAGEL- dressing, wound, drug
MOLECULAR BIOLOGICALS, LLC

keragel®
Wound Gel

STERILE

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0 1 2 3

Rx Only
Single Use
For Topical Dermatological use only.

Description

keragel® is a keratin enriched gel category dressing utilizing keratin technology to create and maintain a moist wound environment. It is presented sterile in a tube for ease of application.

INDICATIONS FOR USE

keragel® is designed for acute/chronic superficial and partial thickness wounds with dry to medium exudate, such as:

- Venous leg ulcers
- Arterial ulcers
- Diabetic foot ulcers
- Pressure ulcers
- Skin graft donor sites
- Sunburns
- First and Second Degree burns

ATTENTION

If the wound is infected, it is advised that you consult with your physician or health care professional.

DIRECTIONS FOR USE

1. Cleanse and debride the wound in accordance with normal procedures.
2. Ensure that the skin surrounding the wound is dry.
3. The tube is opened using the piercer cap to break the nozzle seal. To ensure sterility, sanitise the piercer cap before using.
4. Apply a 3mm to 6mm (1/8inch to 1/4inch) layer of keragel® to cover the entire wound surface.
5. Cover with an appropriate secondary dressing if needed.

RECOMMENDED CARE

The wound should be inspected daily or as indicated by a physician. For wounds that appear dry more gel should be applied to the area. Wounds should be cleansed regularly and new gel applied.

INGREDIENTS

Keratin, phenoxyethanol, hydroxyethylcellulose, glycerol, sorbitol, propylene glycol, lactic acid.

HOW SUPPLIED

keragel[®] 20gm individual tube: NDC 71474-301-20
keragel 5 gm individual tube: NDC 71474-301-05

STORAGE / PRECAUTIONS

keragel[®] should be stored in dry conditions between 0° and 35°C (32° and 95° F).

Do not use if the tube has been damaged prior to use. Sterility is guaranteed until the tube is first opened. Do not re-sterilise.

CAUTION: RX ONLY. Federal law restricts this device to sale by or on the order of a physician.

Manufactured for: Molecular Biologicals, LLC
Pasadena, TX 77505 | 1-844-793-9933

EC	REP
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keragelIT[®] is a registered trademark of
Keraplast Technologies LLC.

The product incorporates patented and/or patent pending
technologies owned by Keraplast Technologies LLC.

Issue Date 8/2017
DWG106/1

PRINCIPAL DISPLAY PANEL - 5 g Tube Box

For Wounds & Burns

Keragel[®]
Enriched With Bioactive Keratin

1x 1 Tube
NDC 71474-301-05
5g/0.2oz
Rx Only

SAMPLE - NOT FOR SALE



KERAGEL

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:71474-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Glycerin (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	100 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71474-301-20	1 in 1 BOX		
1		20 g in 1 TUBE; Type 0: Not a Combination Product		
2	NHRIC:71474-301-10	10 in 1 BOX		

2		20 g in 1 TUBE; Type 0: Not a Combination Product		
3	NHRIC:71474-301-30	30 in 1 BOX		
3		20 g in 1 TUBE; Type 0: Not a Combination Product		
4	NHRIC:71474-301-55	5 in 1 BOX		
4		20 g in 1 TUBE; Type 0: Not a Combination Product		
5	NHRIC:71474-301-05	1 in 1 BOX		
5		5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EXEMPT DEVICE	FRO	02/11/2009	

Labeler - MOLECULAR BIOLOGICALS, LLC (079518915)

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MOLECULAR BIOLOGICALS, LLC