

**KERAGELT- dressing, wound, drug**  
**MOLECULAR BIOLOGICALS, LLC**

-----  
**keragelT®**  
**Wound Gel**

**Rx Only**  
**Single Use**  
**For Topical Dermatological use only.**

**STERILE**

**C E**  
**0 1 2 3**

**Description**

keragelT® 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**

keragelT® 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 keragelT® to cover the entire wound surface daily or three times a day as indicated by a healthcare professional.
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.

## INGREDIENTS

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

## HOW SUPPLIED

kerageIT<sup>®</sup> 20gm individual tube: NDC 71474-302-20

kerageIT<sup>®</sup> 5gm individual tube: NDC 71474-302-05

## STORAGE / PRECAUTIONS

kerageIT<sup>®</sup> 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
----	-----

Keraplast Research Limited, Gerald St., Lincoln 7674, NZ  
Medical Device Consultancy, 7 Pinewood Drive, Ashley Heath,  
Market Drayton, Shropshire TF9 4PA, United Kingdom

kerageIT<sup>®</sup> is a registered trademark of  
Keraplast Technologies LLC.

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

**Issue Date 9/2017**

**DWG107/1**

## PRINCIPAL DISPLAY PANEL - 20 g Tube Box

**kerageIT<sup>®</sup>**

10 x

NDC 71474-302-10

20g/0.7oz

**Rx Only**

MOLECULAR

**BIOLOGICALS**

replicine<sup>™</sup>

keragelT<sup>®</sup>

10 x  NDC 71474-302-10  
20g/0.7oz

**Rx Only**

MOLECULAR  
BIOLOGICALS

  
replicine™

 2018-08



Manufactured for: \_\_\_\_\_

EXP0616U6



Molecular Biologicals, LLC  
Pasadena, TX 77505  
Manufactured by:  
Keraplast Research Limited  
185 Kirk Road  
Christchurch, 7678, 7608, New Zealand (NZL)

## KERAGELT

dressing, wound, drug

### Product Information

<b>Product Type</b>	PRESCRIPTION MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:71474-302
<b>Route of Administration</b>	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:71474-302-20	1 in 1 BOX		
1		20 g in 1 TUBE; Type 0: Not a Combination Product		
2	NHRIC:71474-302-10	10 in 1 BOX		
2		20 g in 1 TUBE; Type 0: Not a Combination Product		
3	NHRIC:71474-302-30	30 in 1 BOX		
3		20 g in 1 TUBE; Type 0: Not a Combination Product		
4	NHRIC:71474-302-05	1 in 1 BOX		
4		5 g in 1 TUBE; Type 0: Not a Combination Product		
5	NHRIC:71474-302-11	10 in 1 BOX		
5		5 g in 1 TUBE; Type 0: Not a Combination Product		
6	NHRIC:71474-302-28	28 in 1 BOX		
6		5 g in 1 TUBE; Type 0: Not a Combination Product		
7	NHRIC:71474-302-55	5 in 1 BOX		
7		20 g in 1 TUBE; Type 0: Not a Combination Product		
8	NHRIC:71474-302-54	5 in 1 BOX		
8		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)

Revised: 10/2018

MOLECULAR BIOLOGICALS, LLC