

**DERMARAD RELIEF- lidocaine emulsion emulsion**  
**RENU LABORATORIES, INC.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----  
**DermaRad Relief Topical Rehydrating Emulsion**

**Active Ingredients**

Allantoin 1%

Lidocaine 4%

**Warnings**

**For External Use Only**

Avoid contact with the eyes.

If condition worsens or if symptoms last more than 7 days or clear up and occur again within a few days, discontinue use and consult a physician. Do not use on:

- Deep or puncture wounds
- Animal bites
- Serious burns

Do not use in large quantities, particularly over raw surfaces or blistered areas.

Do not use on:

- Deep or puncture wounds
- Animal bites
- Serious burns

Do not use in large quantities, particularly over raw surfaces or blistered areas.

**Purpose**

Skin Protectant

Topical Analgesic

DermaMedics LLC, Oklahoma City, OK 73104

[www.dermamedics.com](http://www.dermamedics.com)

1-800-990-6552

**Directions:** Adults and children 2 years of age and older, apply to affected areas no more than 3 to 4 times daily. For children under 2 years of age, consult your physician.

**Uses**

- For the temporary relief of pain and itching associated with minor burns, sunburn, or minor skin irritations.
- Temporarily protects minor burns.
- Temporarily protects and helps relieve chapped or cracked skin.

**Inactive Ingredients:**

Capric/Caprylic Triglyceride, Capryl Glycol, Cetareth-20, Cetearyl Alcohol, Cetyl Alcohol, Deionized Water, Dihydroeugenol,



Dimethicone, Dimethyl Isosorbide, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Glycol Stearate, Hexylene Glycol, Hydroxypropyl Starch Phosphate, Isoeugenyl Acetate, Niacinamide, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Polyacrylate

Crosspolymer-6, PPG/SMDI Copolymer, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium PCA, Squalane, Stearic Acid, Tocopherol.

DermaRad Relief

Topical Rehydrating Emulsion

Keep out of reach of children

																							
<p><b>DermaRad Relief</b> <b>Topical Rehydrating Emulsion</b></p> <p>DermaRad Relief has been specifically designed to relieve discomfort, to protect damaged skin and to address skin appearance problems arising from radiation and other medical treatments.</p>	<p><b>DermaRad</b> <b>Relief</b><sup>®</sup></p>																						
<table border="1"> <thead> <tr> <th colspan="2"><b>Drug Facts</b></th> </tr> </thead> <tbody> <tr> <td><b>Active Ingredients</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Allantoin 1%</td> <td>Skin Protectant</td> </tr> <tr> <td>Lidocaine 4%</td> <td>Topical Analgesic</td> </tr> <tr> <td colspan="2"><b>Uses</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>• For the temporary relief of pain and itching associated with minor burns, sunburn, or minor skin irritations.</li> <li>• Temporarily protects minor burns.</li> <li>• Temporarily protects and helps relieve chapped or cracked skin.</li> </ul> </td> </tr> <tr> <td colspan="2"><b>Warnings</b></td> </tr> <tr> <td colspan="2"><b>For External Use Only</b></td> </tr> <tr> <td colspan="2">           Avoid contact with the eyes.            If condition worsens or if symptoms last more than 7 days or clear up and occur again within a few days, discontinue use and consult a physician. Do not use on:           <ul style="list-style-type: none"> <li>• Deep or puncture wounds</li> <li>• Animal bites</li> <li>• Serious burns</li> </ul>           Do not use in large quantities, particularly over raw surfaces or blistered areas.         </td> </tr> <tr> <td colspan="2"> <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a poison control center right away.         </td> </tr> <tr> <td colspan="2"> <b>Directions:</b> Adults and children 2 years of age and older, apply to affected areas no more than 3 to 4 times daily. For children under 2 years of age, consult your physician.         </td> </tr> </tbody> </table>		<b>Drug Facts</b>		<b>Active Ingredients</b>	<b>Purpose</b>	Allantoin 1%	Skin Protectant	Lidocaine 4%	Topical Analgesic	<b>Uses</b>		<ul style="list-style-type: none"> <li>• For the temporary relief of pain and itching associated with minor burns, sunburn, or minor skin irritations.</li> <li>• Temporarily protects minor burns.</li> <li>• Temporarily protects and helps relieve chapped or cracked skin.</li> </ul>		<b>Warnings</b>		<b>For External Use Only</b>		Avoid contact with the eyes. If condition worsens or if symptoms last more than 7 days or clear up and occur again within a few days, discontinue use and consult a physician. Do not use on: <ul style="list-style-type: none"> <li>• Deep or puncture wounds</li> <li>• Animal bites</li> <li>• Serious burns</li> </ul> Do not use in large quantities, particularly over raw surfaces or blistered areas.		<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a poison control center right away.		<b>Directions:</b> Adults and children 2 years of age and older, apply to affected areas no more than 3 to 4 times daily. For children under 2 years of age, consult your physician.	
<b>Drug Facts</b>																							
<b>Active Ingredients</b>	<b>Purpose</b>																						
Allantoin 1%	Skin Protectant																						
Lidocaine 4%	Topical Analgesic																						
<b>Uses</b>																							
<ul style="list-style-type: none"> <li>• For the temporary relief of pain and itching associated with minor burns, sunburn, or minor skin irritations.</li> <li>• Temporarily protects minor burns.</li> <li>• Temporarily protects and helps relieve chapped or cracked skin.</li> </ul>																							
<b>Warnings</b>																							
<b>For External Use Only</b>																							
Avoid contact with the eyes. If condition worsens or if symptoms last more than 7 days or clear up and occur again within a few days, discontinue use and consult a physician. Do not use on: <ul style="list-style-type: none"> <li>• Deep or puncture wounds</li> <li>• Animal bites</li> <li>• Serious burns</li> </ul> Do not use in large quantities, particularly over raw surfaces or blistered areas.																							
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a poison control center right away.																							
<b>Directions:</b> Adults and children 2 years of age and older, apply to affected areas no more than 3 to 4 times daily. For children under 2 years of age, consult your physician.																							

**Inactive Ingredients:** Capric/Caprylic Triglyceride, Capryl Glycol, Ceteareth-20, Cetearyl Alcohol, Cetyl Alcohol, Deionized Water, Dihydroeugenol, Dimethicone, Dimethyl Isosorbide, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Glycol Stearate, Hexylene Glycol, Hydroxypropyl Starch Phosphate, Isoeugenyl Acetate, Niacinamide, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Polyacrylate Crosspolymer-6, PPG/SMDI Copolymer, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium PCA, Squalane, Stearic Acid, Tocopherol.

DermaMedics LLC, Oklahoma City, OK 73104  
www.dermaedics.com | 1-800-990-6552



## Topical Rehydrating Emulsion

4 FL OZ (118 ml)



PMS 262

# Straight Tuck Box

Size: (W) 2.0 x (H) 6.625" x (D) 2.0"



## DermaRad Relief® Topical Rehydrating Emulsion

DermaRad Relief® has been specifically designed to relieve pain from burns, to protect damaged skin and to address skin appearance problems arising from radiation and other medical treatments.

### Drug Facts

Active Ingredients	Purpose
Allantoin 1%	Skin Protectant
Lidocaine 4%	Topical Anesthetic

### Uses

- For the temporary relief of pain and itching associated with minor burns, sunburn, or minor skin irritations.
- Temporarily protects minor burns.
- Temporarily protects and helps relieve chapped or cracked skin.

### Warnings

#### For External Use Only

- Avoid contact with the eyes.  
If condition worsens or if symptoms last more than 7 days or clear up and occur again within a few days, discontinue use and consult a physician. Do not use on:
- Deep or puncture wounds
  - Animal bites
  - Serious burns

Do not use in large quantities, particularly over raw surfaces or blistered areas.

**Keep out of reach of children** If swallowed, get medical help or contact a poison control center right away.

**Directions:** Adults and children 2 years of age and older, apply to affected areas no more than 3 to 4 times daily. For children under 2 years of age, consult your physician.

**Inactive Ingredients:** Capric/Caprylic Triglyceride, Capryl Glycol, Glycerin-20, Cetearyl Alcohol, Cetyl Alcohol, Deionized Water, Dihydroxyacetone, Dimethylsiloxane, Dimethyl isosorbide, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Glycol Stearate, Hexylene Glycol, Hydroxypropyl Starch Phosphate, Isoeugenyl Acetate, Niacinamide, PEG-100 Stearate, Petrolatum, Phenoxethanol, Polyacrylate Crosspolymer-6, PPG-3Methyl Cocopolymer, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium PCA, Squalane, Stearic Acid, Tocopherol.

Manufactured in the U.S.A. for  
DermaMedics LLC, Oklahoma City, OK 73104  
www.dermamedics.com | 1-800-990-6552



DermaRad Relief® was developed using patented technology discovered at a major university medical school.

DermaRad Relief® has been engineered to provide **high levels of moisturization, pain relief, and skin protection** radiation patients may need throughout their treatments.

This patented formulation contains the skin protectant, **ALLANTOIN** along with the analgesic, **LIDOCAINE**, which relieves pain from burns.

DermaRad Relief® will allow patients to complete all of their treatments with minimal discomfort.



**MAXIMUM STRENGTH**  
4% Lidocaine

**RELIEVES  
PAIN & ITCH**

1% Allantoin  
**PROTECTS  
MINOR BURNS**

with Skin Soothing  
Therosol® Antioxidant  
Complex

4 FL OZ (118 ml)



### DUAL BENEFITS:

**Pain and Itch Relief and  
Skin Protection From Minor:**

- Burns Sunburn
- Skin Irritation
- Cuts and Scrapes

**High Levels of  
Moisturizing Oils,  
Humectants and  
Antioxidants  
Soothe Damaged Skin  
and Keep it Hydrated  
to Allow Healing**

**Trusted by  
Radiation Patients  
for Over 10 years**

SELF ADHESIVE TAPE

COLOR IN USE:

PANTONE 262 C

BLACK

SILVER FOILING

# DERMARAD RELIEF

lidocaine emulsion emulsion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76348-720
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	1.18 g in 118 mL
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4.72 g in 118 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ALPHA-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>DIHYDROEUGENOL</b> (UNII: A3XE712277)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PPG-51/SMDI COPOLYMER</b> (UNII: KQ9JG3O3YA)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>WHITE PETROLATUM</b> (UNII: B6E5W8RQJ4)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)	
<b>AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S)</b> (UNII: Q7UI015FF9)	
<b>GLYCERYL STEARATE/PEG-100 STEARATE</b> (UNII: RD25J5V947)	
<b>GLYCOL STEARATE</b> (UNII: 0324G66D0E)	
<b>ISOEUGENYL ACETATE</b> (UNII: 9DF21GI8W6)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>HYDROXYPROPYL CORN STARCH (5% SUBSTITUTION BY WEIGHT)</b> (UNII: 9M44R3409A)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-720-01	1 in 1 BOX	01/03/2022	
1	NDC:76348-720-04	118 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/03/2022	

**Labeler** - RENU LABORATORIES, INC. (945739449)

## Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-720)

Revised: 1/2023

RENU LABORATORIES, INC.