

DERMARAD RELIEF POST RADIATION CALMING- lidocaine 3 percent liquid
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 Post Radiation Calming Serum with 3% Lidocaine

Active Ingredient

Lidocaine 3%

Purpose

External Analgesic

Uses

Temporarily relieves pain and itching due to

- sunburn
- minor burns
- minor cuts
- minor skin irritations

Warnings

For external use only

Stop use and ask a doctor if

- Condition gets worse
- Symptoms persist for more than 7 days
- Symptoms clear up and occur again in a few days

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 and older apply to affected area not more than 3 to 4 times daily
- children under 2 years of age : ask a doctor

Inactive Ingredients:

Cyclopentasiloxane, Dihydroeugenol, Dimethicone, Dimethiconol, Dimethicone/Vinyl Dimethicone Crosspolymer, Helianthus Annuus (Sunflower) Seed Oil, Isoeugenyl Acetate, Petrolatum, Simmondsia Chinensis (Jojoba) Seed Oil, Squalane.

Manufactured in the U.S.A. for Dermamedics, LLC

Oklahoma City, OK 73112

www.dermamedics.com

1 800 990 6552

DERMAMEDICS

Post Radiation

Calming

Serum with

3 % Lidocaine

When using this product

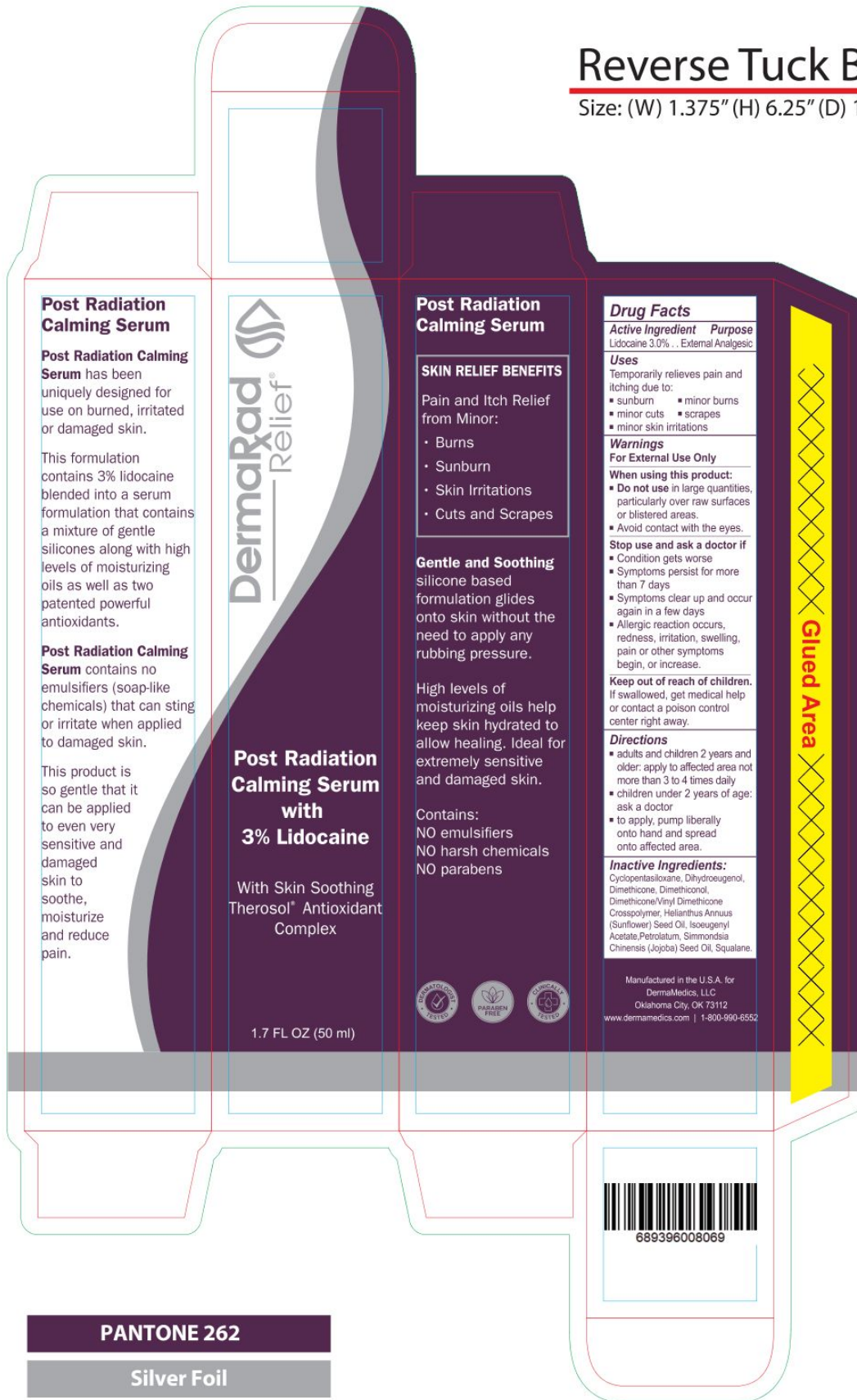
Do not use in large quantities particularly over raw surfaces or blistered areas

Avoid contact with the eyes

PRODUCT BOX FOR POST RADIATION CALMING SERUM

Reverse Tuck Box

Size: (W) 1.375" (H) 6.25" (D) 1.375"



Post Radiation Calming Serum

Post Radiation Calming Serum has been uniquely designed for use on burned, irritated or damaged skin.

This formulation contains 3% lidocaine blended into a serum formulation that contains a mixture of gentle silicones along with high levels of moisturizing oils as well as two patented powerful antioxidants.

Post Radiation Calming Serum contains no emulsifiers (soap-like chemicals) that can sting or irritate when applied to damaged skin.

This product is so gentle that it can be applied to even very sensitive and damaged skin to soothe, moisturize and reduce pain.

DermaRad
— Relief

Post Radiation Calming Serum with 3% Lidocaine

With Skin Soothing Therosol® Antioxidant Complex

1.7 FL OZ (50 ml)

Post Radiation Calming Serum

SKIN RELIEF BENEFITS

Pain and Itch Relief from Minor:

- Burns
- Sunburn
- Skin Irritations
- Cuts and Scrapes

Gentle and Soothing silicone based formulation glides onto skin without the need to apply any rubbing pressure.

High levels of moisturizing oils help keep skin hydrated to allow healing. Ideal for extremely sensitive and damaged skin.

Contains:
NO emulsifiers
NO harsh chemicals
NO parabens



Drug Facts

Active Ingredient Purpose
Lidocaine 3.0% . . . External Analgesic

Uses

Temporarily relieves pain and itching due to:

- sunburn
- minor burns
- minor cuts
- scrapes
- minor skin irritations

Warnings

For External Use Only

When using this product:

- **Do not use** in large quantities, particularly over raw surfaces or blistered areas.
- Avoid contact with the eyes.

Stop use and ask a doctor if

- Condition gets worse
- Symptoms persist for more than 7 days
- Symptoms clear up and occur again in a few days
- Allergic reaction occurs, redness, irritation, swelling, pain or other symptoms begin, or increase.

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 and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor
- to apply, pump liberally onto hand and spread onto affected area.

Inactive Ingredients:

Cyclopentasiloxane, Dihydroxyacetone, Dimethicone, Dimethiconol, Dimethicone/Vinyl Dimethicone Crosspolymer, Helianthus Annuus (Sunflower) Seed Oil, Isoeugenyl Acetate, Petrolatum, Simmondsia Chinensis (Jojoba) Seed Oil, Squalane.

Manufactured in the U.S.A. for
DermaMedics, LLC
Oklahoma City, OK 73112
www.dermamedics.com | 1-800-990-6552

Glued Area

PANTONE 262

Silver Foil



689396008069

41mmX66mm



DermaRad Relief

Post Radiation
Calming Serum
with 3% Lidocaine

With Skin Soothing
Therosol[®] Antioxidant
Complex

1.7 FL OZ (50 ml)

| Drug Facts | |
|--|--------------------|
| Active Ingredient | Purpose |
| Lidocaine 3.0% | External Analgesic |
| Uses | |
| Temporarily relieves pain and itching due to: | |
| • sunburn • minor burns • minor cuts • minor skin irritations | |
| Warnings | |
| For External Use Only | |
| When using this product: | |
| • Do not use in large quantities, particularly over raw surfaces or blistered areas. | |
| • Avoid contact with the eyes. | |
| Stop use and ask a doctor if | |
| • Condition gets worse | |
| • Symptoms persist for more than 7 days | |
| • Symptoms clear up and occur again in a few days | |
| 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 and older: apply to affected area not more than 3 to 4 times daily | |
| • children under 2 years of age: ask a doctor | |
| Inactive Ingredients: | |
| Cyclopentasiloxane, Dihydroeugenol, Dimethicone, Dimethiconol, Dimethicone/Vinyl Dimethicone Crosspolymer, Helianthus Annuus (Sunflower) Seed Oil, Isoeugenyl Acetate, Petrolatum, Simmondsia Chinensis (Jojoba) Seed Oil, Squalane. | |
| Manufactured in the U.S.A. for DermaMedics, LLC Oklahoma City, OK 73112 www.dermamedics.com 1-800-990-6552 | |

107mmX76mm



DERMARAD RELIEF POST RADIATION CALMING

lidocaine 3 percent liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76348-970 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 1.5 g in 50 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| ISOEUGENYL ACETATE (UNII: 9DF21GI8W6) | |
| SQUALANE (UNII: GW89575KF9) | |
| DIHYDROEUGENOL (UNII: A3XE712277) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:76348-970-01 | 1 in 1 BOX | 08/08/2022 | |
| 1 | NDC:76348-970-50 | 50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M015 | 08/08/2022 | |

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| Renu Laboratories, Inc. | | 945739449 | manufacture(76348-970) |

Revised: 8/2022

Renu Laboratories, Inc.