

RADX- lidocaine lotion
Cosmetic Specialty Labs, 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.

Active Ingredients

Lidocaine 2%

Purpose

Topical Anesthetic

Uses

- Provides immediate pain relief to skin undergoing radiation therapy
- Helps reduce inflammation
- Hydrates skin into the 2nd and 3rd dermal layers
- Helps Promote cell regeneration

Warnings

For external use only.

keep out of eyes. Rinse with water to remove.

Stop us and ask a doctor if rash occurs.

Keep out of reach of children. If the product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply immediately following treatments, increasing to multiple times daily if skin becomes irritated, painful or inflamed.
- May be applied as frequently as once per hour.

Inactive Ingredients

Water, Cetearyl Olivat, Sorbitan Olivat, Helianthus Annuus (Sunflower) Seed Oil, Cocos Nucifera (Coconut) Oil, Cetyl Phosphate, Cetearyl Alcohol, Leuconostoc/Radish Root Ferment Filtrate, Hippophae Rhamnoides (Sea Buckthorn) Extract, Hydrogenated Ethylhexyl Olivat, Hydrogenated Olive Oil Unsaponifiables, Carica Papaya (Papaya) Seed Oil, Beta-Glucan, C12-C15 Alkyl Benzoate, Tocopheryl Linoleate/Oleate, Sodium Hyaluronate, Allantoin, Aloe Barbadensis, Bromelain, Xanthan Gum, Hydrolyzed Silk

Carefree Skincare



Restorative Healer

FACES &
OTHER PLACES®

post treatment
immediate relief
2% lidocaine
laser.peel.sugar.wax

NET WT. 3.3 OZ (100 ML)

Anti-Redness • Anti-Inflammatory
Paraben Free • 1% Beta Glucan
1% Hyaluronic Acid • Sea Buckthorn
Papaya Seed • Bromelain
Hydrolyzed Silk

| Active Ingredients | Purpose |
|---|--------------------|
| Lidocaine 2% | Topical Anesthetic |
| Uses | |
| <ul style="list-style-type: none"> • Provides immediate pain relief to skin undergoing radiation therapy • Helps reduce inflammation • Hydrates skin into the 2nd and 3rd dermal layers • Helps Promote cell regeneration | |
| Warnings | |
| <p>For external use only. When using this product keep out of eyes. Rinse with water to remove. Stop use and seek a doctor if rash occurs. Keep out of reach of children. If the product is swallowed, get medical help or contact a Poison Control Center right away.</p> | |
| Directions | |
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| Inactive Ingredients | |
| <p>Water, Cetearyl Olivate, Sorbitan Olivate, Helianthus Annuus (Sunflower) Seed Oil, Cocos Nucifera (Coconut) Oil, Cetyl Phosphate, Cetearyl Alcohol, Laurocystolic Acid, Radish Root Ferment Filtrate, Hippocistaminol (Sea buckthorn) Extract, Hydrogenated Ethylhexyl Olivate, Hydrogenated Olive Oil Unsaponified, Carica Papaya (Papaya) Seed Oil, Beta-Glucan, C12-15 Alkyl Benzoate, Tocopherol Linoleate/Distoleate, Sodium Hyaluronate, Allantoin, Aloe Barbadensis, Bromelain, Xanthan Gum, Hydrolyzed Silk.</p> | |
| Questions or Comments? Call or email us. | |

Made in USA

NDC # 58133-050-03

Item# 490

Distributed by:
Carefree Skincare
Austin, TX 78641
512-827-2433
info@sunblocks.com
www.sunblocks.com



RADX

lidocaine lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58133-650 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 2 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| .ALPHA.-TOCOPHEROL LINOLEATE, D- (UNII: G0N132Q0ED) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| SILK, ACID HYDROLYZED (1000 MW) (UNII: 8549W658QV) | |
| ALLANTOIN (UNII: 344S277G0Z) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| PAPAYA (UNII: KU94FIY6JB) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| ETHYLHEXYL OLEATE (UNII: R34927QY59) | |
| CETEARYL OLIVATE (UNII: 58B69Q84JO) | |
| CETYL PHOSPHATE (UNII: VT07D6X67O) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J) | |
| HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95) | |
| LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458) | |
| SODIUM CARBOXYMETHYL .BETA.-GLUCAN (DS 0.65-0.85) (UNII: 2YGO1190AP) | |
| FRUIT BROMELAIN (UNII: F0ZCA6O9QT) | |
| WATER (UNII: 059QF0KO0R) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| SORBITAN OLIVATE (UNII: MDL271E3GR) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58133-650-03 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 07/30/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part348 | 07/30/2021 | |

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|----------------|---------------|---|
| Cosmetic Specialty Labs, Inc. | | 032973000 | manufacture(58133-650) , label(58133-650) , pack(58133-650) |

Revised: 8/2021

Cosmetic Specialty Labs, Inc.