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 Incredients

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

RADX®

Metal Free • Paraben Free

radiation therapy

Immediate Relief

2% Lidocaine

Drug Facts

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Questions or Comments? Call or email us.

1-866-411-RADX (7239) NDC 58133-650-33

Radx Radiation Therapy
Austin, Tx. 78641
512-827-2433 **info@radxhelps.com**

anti-inflammatory

net wt. 3.3 oz / 100 ml

Made in USA Item #411

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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:58133-650-33	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: 7/2021 Cosmetic Specialty Labs, Inc.