

BURN SOLUTION CREAM- tetracaine cream cream
Burn Solution Foundations

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.

Drug Facts

Topical Burn Cream plus Pain Relief

Active ingredient

Tetracaine (1.0%).....Pain & Itch Relief

Purpose

For temporary relief of minor aches and pains of muscles and joints commonly associated with backache, arthritis, strains, bruises, sprains, and burns

Indications

- For cooling, deep-penetrating pain relief, apply a thin layer sparingly to affected areas.
- Apply up to 3 times daily

Warnings

- Not for use on children under 2 years old except as directed by a doctor.
- Avoid contact with the eyes.
- For external use only.
- If irritation develops and persists, discontinue use and consult a doctor.
- If condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use and consult a doctor.

KEEP OUT OF REACH OF CHILDREN

Directions

- Apply this product topically to affected areas.
- Use up to 3 times daily.
- Use only as directed.

Other Information

External Anesthetic

Inactive Ingredients

Water, Stearic Acid, Lauramide DEA, Beeswax, Propylene Glycol, Sodium Tetraborate, Sodium Lauryl Sulfate, Diazolidinyl Urea, Methylparaben, Propylparaben, Triethanolamine, Eucalyptus Oil.

Questions or Comments

Burn Solution Foundation
Land O Lakes, FL
888.368.0555
<http://relief-roller.com>

starell

Specially designed to give first responders and medical professionals relief from minor abrasions, irritation, and discomfort associated with lengthy PPE use. Apply before PPE use to prevent discomfort and irritation.

No-Touch Roll-On
This delivery system allows you to safely apply without touching the product or the applicator tip with your fingers. Do not share this product with anyone else after opening.



0.20 fl. oz.
NDC 70704-212-20
Patented



Starell[™]
ReliefRoller

Maximum-Strength Anesthetic
Relieves Chafing & Irritation



This product will cause numbing wherever it touches. Avoid contact with eyes and lips. If accidentally applied, rinse with plenty of water and if convenient, wash with soap and water.

Starell's Story
Dr. Bruce Miller introduced this product to help treat severe burns and to help burn victims heal without scarring. His success in that venture introduced him to nurses, doctors, and first responders who are on the front lines of the Covid-19 pandemic. This product is intended to help them while they help us.

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BURN SOLUTION CREAM

tetracaine cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70704-212
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACAINE (UNII: 0619F35CGV) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM BORATE ANHYDROUS (UNII: 8191EN8ZMD)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70704-212-20	1 in 1 BOX	02/02/2021	
1		5.6 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	02/02/2021	

Labeler - Burn Solution Foundations (085996883)**Establishment**

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(70704-212)

