

## **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.*

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## **DRUG FACTS**

Topical Burn Cream Plus Pain Relief

### **Active Ingredient Purpose**

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

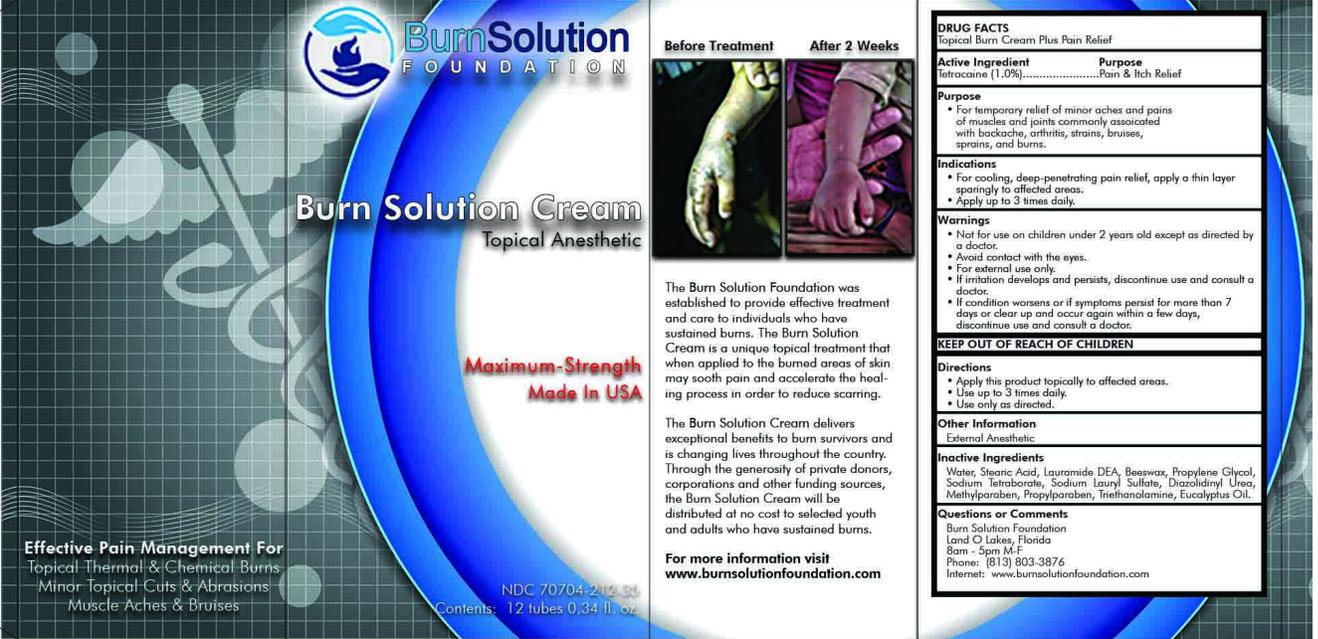
Land O Lakes, Florida

8am - 5pm M-F

Phone: (813) 803-3876

Internet: [www.burnsolutionfoundation.com](http://www.burnsolutionfoundation.com)

Recommended for minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.



**BurnSolution**  
FOUNDATION

**Burn Solution Cream**  
Topical Anesthetic

**Maximum-Strength**  
**Made In USA**

**Effective Pain Management For**  
Topical Thermal & Chemical Burns  
Minor Topical Cuts & Abrasions  
Muscle Aches & Bruises

**Before Treatment**      **After 2 Weeks**

The Burn Solution Foundation was established to provide effective treatment and care to individuals who have sustained burns. The Burn Solution Cream is a unique topical treatment that when applied to the burned areas of skin may soothe pain and accelerate the healing process in order to reduce scarring.

The Burn Solution Cream delivers exceptional benefits to burn survivors and is changing lives throughout the country. Through the generosity of private donors, corporations and other funding sources, the Burn Solution Cream will be distributed at no cost to selected youth and adults who have sustained burns.

**For more information visit**  
[www.burnsolutionfoundation.com](http://www.burnsolutionfoundation.com)

NDC 70704-212-01  
Contents: 12 tubes 0.34 fl. oz.

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Active Ingredient	Purpose
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Questions or Comments	
Burn Solution Foundation Land O Lakes, Florida 8am - 5pm M-F Phone: (813) 803-3876 Internet: <a href="http://www.burnsolutionfoundation.com">www.burnsolutionfoundation.com</a>	

## BURN SOLUTION CREAM

tetracaine cream cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70704-212
<b>Route of Administration</b>	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
SODIUM BORATE ANHYDROUS (UNII: 8191EN8ZMD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A218C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70704-212-35	12 in 1 BOX	08/23/2016	
1	NDC:70704-212-34	10 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	08/23/2016	

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

### Establishment

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