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 Purpose

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

Purpose

• For temporary relief of minor aches and pains of muscles and joints commonly assoicated 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

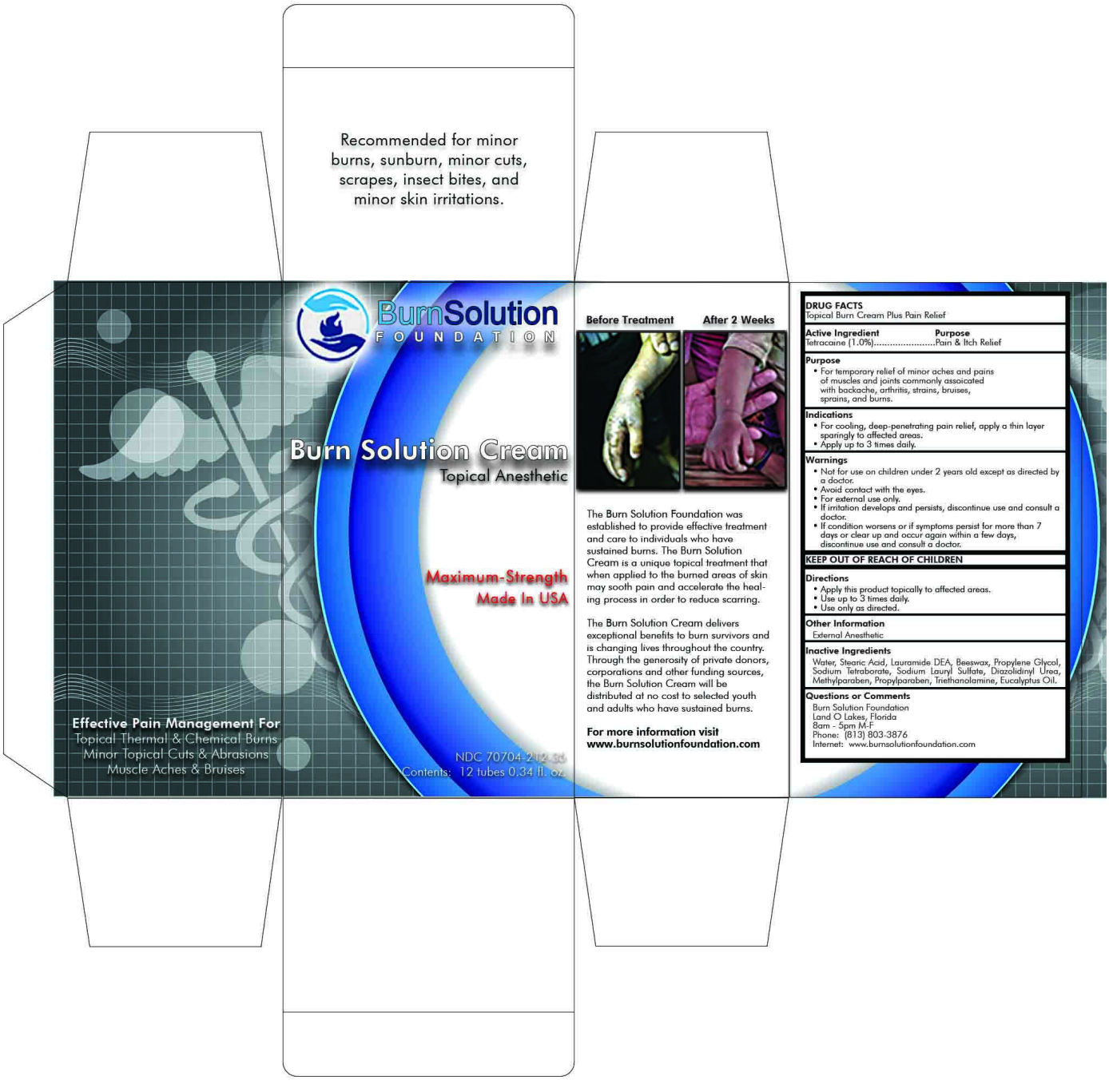
Burn Solution Foundation

Land O Lakes, Florida

8am - 5pm M-F

Phone: (813) 803-3876

Internet: www.burnsolutionfoundation.com



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
SODIUM BORATE ANHYDROUS (UNII: 8191EN8ZMD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (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)