

TOP SAFETY FIRST AID BURN CREAM- lidocaine cream

Top Safety Products Company 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.

TS-605-365T Top Safety First Aid Burn Cream NDC 51395-412-01

Active Ingredients

Active Ingredient	Purpose
Lidocaine HCL 0.5%	Topical Analgesic
Benzalkonium Chloride 0.13%	Topical Antiseptic

Purpose

Temporary relief of pain and itching.

Uses

For temporary relief of pain and itching associated with:

- Sunburn
- Minor burns,
- Insect bites,
- Minor skin irritation,
- Cuts and
- Scrapes

Warnings

☐FOR EXTERNAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

☐KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

Stop Use

☐Stop Use and ask a doctor:

- ☐☐If condition worsens or,
- if symptoms persist for more than 7 days or clear up and occur again in a few days.
- If pregnant or breast feeding, ask a health professional before use.

Do Not Use

☐Do Not Use:

- In the eyes
- Over large areas of the body or on deep puncture wounds, animal bites or serious burns.
- In large quantities, particularly over raw surfaces or blistered areas.

Directions

Adults and children 2 years and over:

- clean the affected area
- apply a small amount of this product on the area 3 or 4 times daily.
- may be covered with a sterile bandage

Children under 2 years

- consult a doctor

Inactive ingredients

Butylated hydroxy toluene, Cetomacrogol, Cetostearyl alcohol, Dimethicone, Glycerine, Glyceryl monostearate, Isopropyl myristate, Methylcellulose, Purified water, Sodium EDTA, Sodium methylparaben, Sodium propylparaben

Other Information

Other Information

- store in a cool, dry area
- 59o to 79o F (15o to 25o C)
- Tamper evident sealed packets do not use any open or torn packets

Principal Display Panel

Top Safety First Aid Burn Cream

Top Safety.jpg



TOP SAFETY FIRST AID BURN CREAM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51395-412
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.13 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
METHYLCELLULOSE (25 MPA.S) (UNII: B155GG2WLI)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
CETETH-20 (UNII: I835H2IHHX)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)				
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)				
GLYCERIN (UNII: PDC6A3C0OX)				
EDETATE SODIUM (UNII: MP1J8420LU)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51395-412-01	2000 in 1 BOX	02/16/2016	
1		0.9 g in 1 PACKET; 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	02/07/2016	

Labeler - Top Safety Products Company Inc (627999956)

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