

2677 FIRST AID BURN CREAM- 2677 first aid burn cream cream
ProStat First Aid LLC

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.

2677 First Aid Burn Cream

Active Ingredient

Lidocaine Hydrochloride 0.5%

Purpose

Topical Analgesic

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Topical Antiseptic

Use(s)

For temporary relief of pain and itching associated with:

- Sunburn • Minor burns • Insect bites • Cuts • Scrapes

Warnings

For External Use Only

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

Stop use and ask a doctor if

- The condition gets worse • Condition clears up and recurs within a few days • Condition persists for more than 7 days

If pregnant or breast feeding

Ask a healthcare professional before use.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions**Adults and children 2 years and older:**

- Clean the affected area
- Apply a small amount of this product on the area 3 to 4 times daily
- May be covered with a sterile bandage

Children under 2 years: • Consult a doctor

Other Information

- Store in a cool, dry area 15°-25° C (59°-77° F)
- Tamper evident sealed packets
- Do not use any opened or torn packets

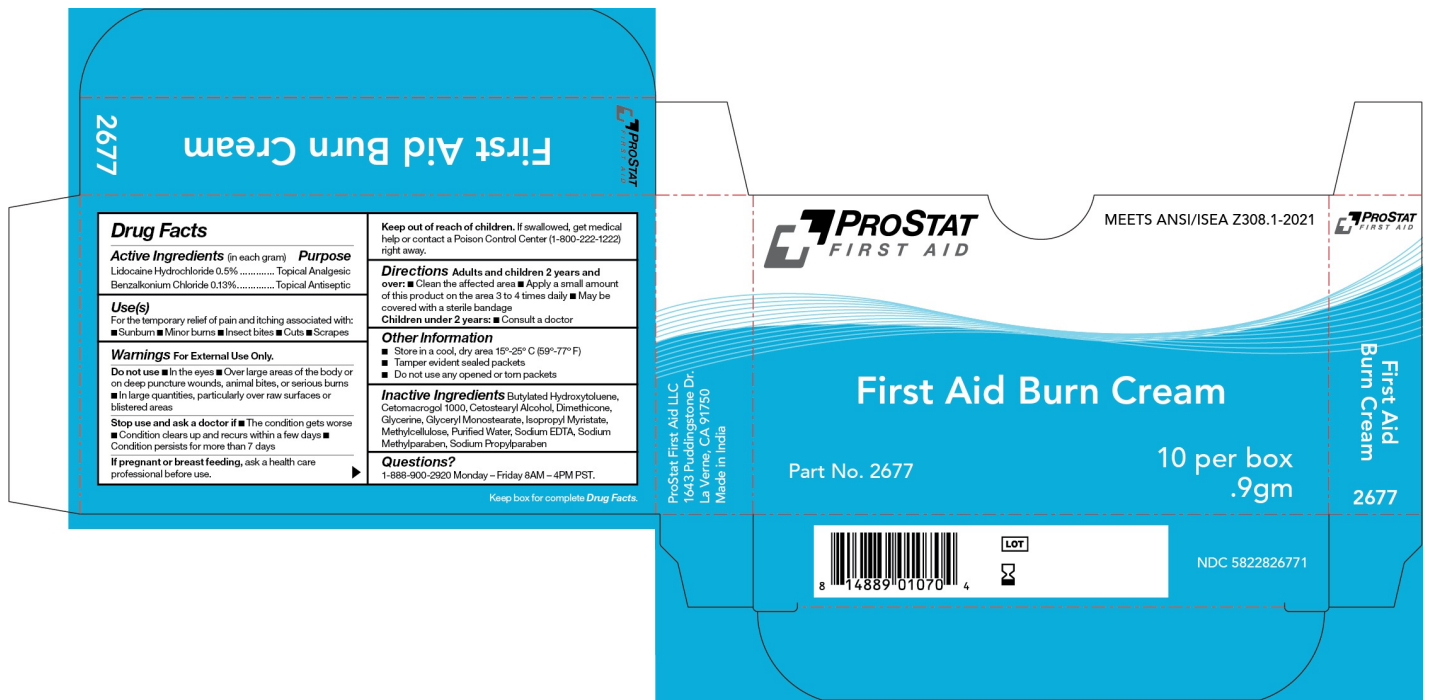
Inactive Ingredients

Butylated Hydroxytoluene, Cetomacrogol 1000, Cetostearyl Alcohol, Dimethicone, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Methylcellulose, Purified Water, Sodium EDTA, Sodium Methylparaben, Sodium Propylparaben

Questions?

1-888-900-2920 Monday - Friday 8AM - 4PM PST

Label



PROSTAT First Aid Burn Cream

2677 FIRST AID BURN CREAM

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58228-2677
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	13 mg in 10000 mg
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII: 98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	50 mg in 10000 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLCELLULOSE (4000 MPA.S) (UNII: MRJ667KA5E)	
CETETH-20 (UNII: I835H2IHHX)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)

Product Characteristics

Color		Score	
Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-2677-1	100 in 1 CASE	07/21/2023	
1		10 in 1 BOX		
1		900 mg 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	07/21/2023	

Labeler - ProStat First Aid LLC (061263699)

Registrant - Dynarex Corporation (008124539)

Revised: 6/2023

ProStat First Aid LLC