

**FIRST AID BURN CREAM- 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.*

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**2044 First Aid Burn Cream**

***Active Ingredient***

Benzalkonium Chloride 0.13%

***Active Ingredient***

Lidocaine Hydrochloride 0.5%

***Purpose***

Benzalkonium Chloride Topical Antiseptic

Lidocaine Hydrochloride Topical Analgesic

***Use(s)***

- For the temporary relief of pain and itching associated with:
- Sunburn • Minor burns • Insect bites • Minor skin irritation • 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 health care 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 over:**

- 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

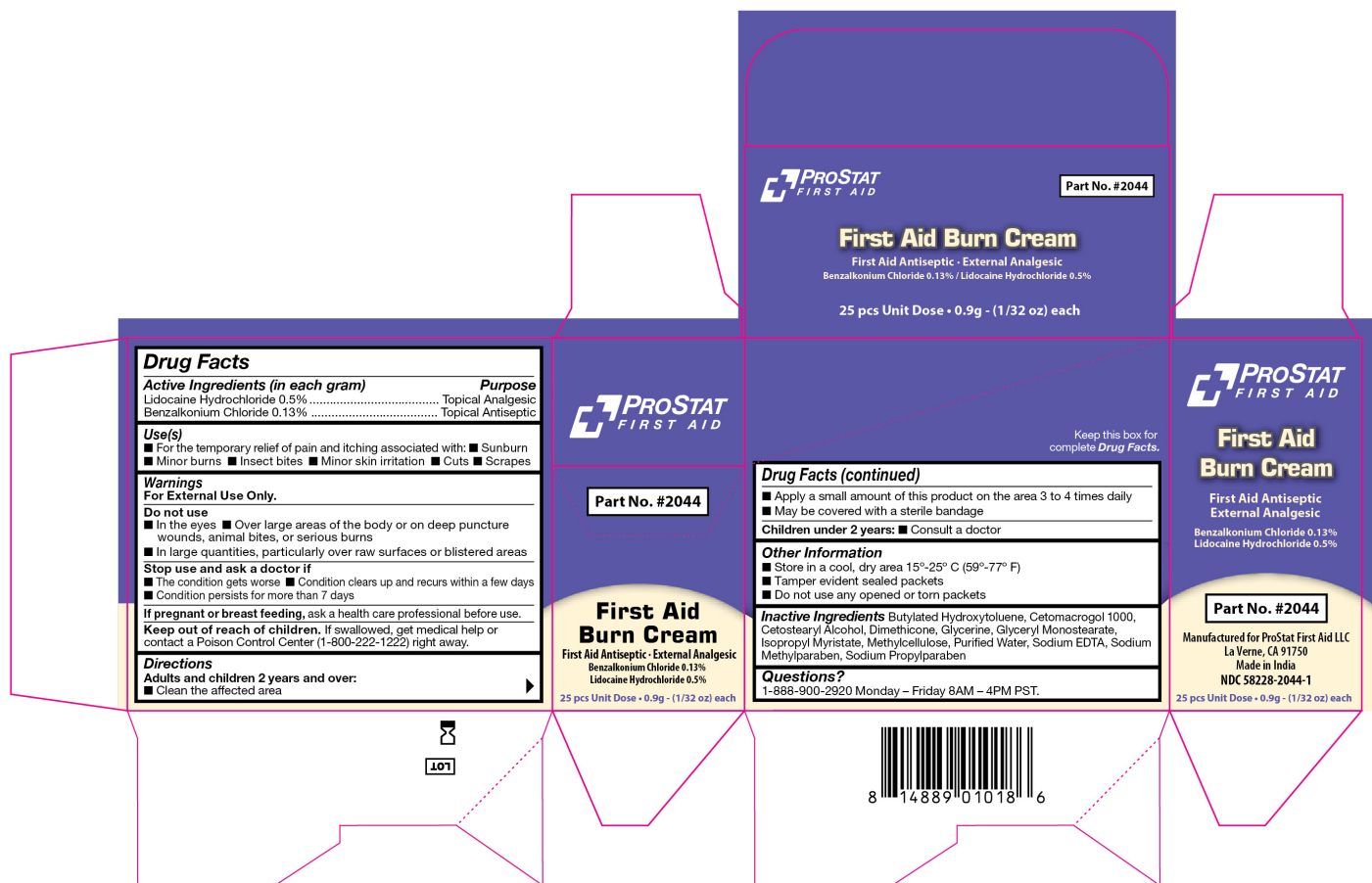
***Inactive Ingredients***

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

***Questions?***

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

***Label***



## First Aid Burn Cream

### FIRST AID BURN CREAM

first aid burn cream cream

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58228-2044
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (C12-C16)</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (C12-C16)	0.13 g in 100 g
<b>LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A)</b> (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g

#### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)</b>	
<b>CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)</b>	
<b>GLYCERIN (UNII: PDC6A3C0OX)</b>	
<b>GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)</b>	
<b>ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)</b>	

<b>METHYLPARABEN SODIUM</b> (UNII: CR6K9C2NHK)	
<b>PROPYLPARABEN SODIUM</b> (UNII: 625NNB0G9N)	
<b>METHYLCELLULOSE (4000 CPS)</b> (UNII: MRJ667KA5E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>CETETH-20</b> (UNII: I835H2IHHX)	
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	FREEFORM	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-2044-2	1800 in 1 CASE	04/10/2023	
1	NDC:58228-2044-1	25 in 1 BOX		
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	04/10/2023	

**Labeler** - ProStat First Aid LLC (061263699)

Revised: 3/2023

ProStat First Aid LLC