

**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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**PS-2309 First Aid Burn Cream**

***Active Ingredient***

Lidocaine HCl 0.5%

***Purpose***

Topical Analgesic

***Active Ingredient***

Benzalkonium Chloride 0.13%

***Purpose***

Topical Antiseptic

***Use(s)***

For the 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 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***

# PROSTAT

## Drug Facts

**Active Ingredients** (in each gram) **Purpose**  
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Benzalkonium Chloride 0.13% ..... Topical Antiseptic

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CODE: 2309

ITEM: PROSTAT FIRST AID BURN CREAM  
0.9GM

QTY: 2,000 SACHETS/CASE

LOT #:

EXP. DATE:

NET WT:

GROSS WT:

MADE IN INDIA

Keep box for complete **Drug Facts**.

PS-2309 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:58228-2309 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                        |          |
| <b>EDETATE SODIUM</b> (UNII: MP1J8420LU)               |          |
| <b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)     |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)        |          |
| <b>METHYLCELLULOSE (4000 MPA.S)</b> (UNII: MRJ667KA5E) |          |
| <b>PROPYLPARABEN SODIUM</b> (UNII: 625NNB0G9N)         |          |
| <b>ISOPROPYL MYRISTATE</b> (UNII: ORE8K4LNJS)          |          |
| <b>METHYLPARABEN SODIUM</b> (UNII: CR6K9C2NHK)         |          |
| <b>CETETH-20</b> (UNII: I835H2IHHX)                    |          |
| <b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)              |          |

|   |  |
|---|--|
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)            |  |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S) |  |

### 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:58228-2309-1 | 2000 in 1 CARTON                                      | 07/31/2023           |                    |
| 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                                  | 07/31/2023           |                    |

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

**Registrant** - Dynarex Corporation (008124539)

Revised: 7/2023

ProStat First Aid LLC