

PROSTAT FIRST AID BURN EASE, 0.9G- lidocaine gel
ProStat First Aid LLC

58228-2012-1 Prostat 8610 Burn Ease Burn gel 0.9g

Active Ingredient

Lidocaine Hydrochloride 2%

Purpose

Topical Pain Relief

Use(s)

Temporary pain relief associated with minor burns

Warnings

For External Use Only

Do not use

- any opened or torn packets
- in large quantities, particularly over raw or blistered areas
- Near eyes. If this happens, rinse thoroughly with water

Stop use and ask a doctor if

- Condition worsens or persists for more than 7 days or clears up and returns

Keep out of reach of children

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

Directions

Apply an even layer of burn gel over cleaned affected area not more than 3-4 times daily
Not to be used on children under 12 years of age

Other Information

- store at 68-77F (20-25C)
- tamper evident sealed packets

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Aminomethyl propanol, Carbomer, Ethylhexylglycerin, Maltodextrin, Menthol, Polyethylene glycol, Phenoxyethanol, Tocopheryl Acetate, Water

Questions?

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



PROSTAT FIRST AID BURN EASE, 0.9G

lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58228-2012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z 41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII:	

4Q93RCW27E)	
AMINOMETHYL PROPANOL (UNII: LU49E6626Q)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MENTHOL (UNII: L7T10EIP3A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K0OR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)	

Product Characteristics

Color		Score	
Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-2012-1	900 in 1 CARTON	09/30/2025	
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 Drug	M017	09/30/2025	

Labeler - ProStat First Aid LLC (061263699)

Registrant - Nantong Health & Beyond Hygienic Products Inc. (421280161)

Establishment

Name	Address	ID/FEI	Business Operations
Nantong Health & Beyond Hygienic Products Inc.		421280161	manufacture(58228-2012)