1168- 1168 burn spray spray
Dynarex Corporation

1168 Burn Spray

Active Ingredient

Lidocaine Hydrochloride 2%

Purpose

Topical Analgesic

Use(s)

For the temporary relief of pain associated with minor burns

Warnings

For External Use Only

Do not use

• Over large areas of the body, particularly over raw surfaces, or blistered areas

• Near eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if

Condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days

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 12 years of age and older:** Spray an even layer of burn spray over cleaned, affected area not more than 3 to 4 times daily.

• **Children under 12 years of age:** Consult a doctor before use

Other Information

• Store at 20º-25ºC (68º-77°F)

Inactive Ingredients

Glycerin, Hydroxypropyl Methyl Cellulose, Melaleuca Alterniflia (Tea Tree) Leaf Oil, Octoxynol 9, PEG-40 Hydrogenated Castor Oil, Phenoxyethanol, Propylene Glycol, Purified Water, Triethanolamine

Questions?

1-888-Dynarex Monday - Friday, 9AM - 5PM EST

Label

1168 Label

1168

1168 burn spray spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.02 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color		**Score**	
Shape	FREEFORM	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-013-05	24 in 1 CASE	02/29/2024	
1	NDC:67777-013-06	59.1 mL in 1 BOTTLE, SPRAY; 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	02/29/2024	

Labeler - Dynarex Corporation (008124539)

Revised: 2/2024 Dynarex Corporation