MYDERM- lidocaine gel Inspec Solutions LLC.

MyDerm Pain Reliever Aloe Gel Lidocaine HCI 0.5%

Active Ingredient

Lidocaine 0.5%

Lidocaine 0.5% Pain Reliever

Temporary relief of pain and itching due to

- sunburn - minor burn - insect bites - minor cuts - scraps

Warnings

For external use only

When using this product keep out of eyes

Rinse with warter to remove

Sop use and ask a doctor

system persist for more than 7 days.

Keep out of reach of children. If product is swallowed, get medical help or contact a poison control center right away.

Direction

Adults and children 2 years and older: aooly to affected area not more that 3-4 times a day

Children under 2 years of age: consult a physician.

Inactive Ingredients: Aloe Barbadensis Leaf Extract, Carbomer, Diazolidinyl Urea, Disodium EDTA, Glycerin, Isopropyl Alcohol, Menthol, Polysorbate 80, Propylene Glycol, Triethanolamine, Water, Yellow 5.



Drug Facts

Active ingredient
Lidocaine Hydrochloride 0.5%...

PurposePain Reliever

Uses

Temporary relief of pain and itching due to
• sunburn • minor burns • insect bites • minor cuts • scrapes

Warnings For external use only

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor • symptoms persist for more than 7 days.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • Adults and children 2 years and older: Apply to affected area not more than 3-4 times a day. • Children under 2 years of age: consult a physician.

Other information • protect this product from excessive heat and direct sun • may stain fabrics.

Inactive ingredients Aloe Barbadensis Leaf Extract, Blue 1, Carbomer, Diazolidinyl Urea, Disodium EDTA, Glycerin, Isopropyl Alcohol, Menthol, Polysorbate 80, Propylene Glycol, Triethanolamine, Water, Yellow 5.

Distributed by: **MyDerm** Ormond Beach, FL 32174 866.467.7320



lidocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72667-008

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE UNII:98PI200987) LIDOCAINE HYDROCHLORIDE ANHYDROUS 0.5 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
MENTHOL (UNII: L7T10EIP3A)		
PROPYLENE GLYCOL 2-STEARATE (UNII: 5317AOR1RX)		
TROLAMINE SALICYLATE (UNII: H8O4040BHD)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CARBOMER 1342 (UNII: 809Y72KV36)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
DISODIUM HEDTA (UNII: KME849MC7A)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
FD&C YELLOW NO. 5 FREE ACID (UNII: 6TP696149N)		

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:72667- 008-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/26/2019			
2	NDC:72667- 008-09	592 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/26/2019			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M017	02/26/2019			

Labeler - Inspec Solutions LLC. (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(72667-008)

Revised: 7/2025 Inspec Solutions LLC.