

MYDERM- lidocaine gel
Inspec Solutions 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.

MyDerm Pain Reliever Aloe Gel Lidocaine HCl 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 water to remove

Stop use and ask a doctor

if 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.

Direction

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.

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



#sun
by MyDerm™

pain reliever
ALOE GEL
Lidocaine HCl 0.5%



Cooling pain relief associated with:

- Sunburn
- Cuts & scrapes
- Insect bites
- Minor burns

8 FL OZ (237 mL)

Drug Facts

Active ingredient	Purpose
Lidocaine Hydrochloride 0.5%	Pain 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, Diazolidimyl 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



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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	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: 6OZP39ZG8H)	
FD&C YELLOW NO. 5 FREE ACID (UNII: 6TP696149N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-008-01	237 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 not final	part348	02/26/2019	

Labeler - Inspec Solutions LLC. (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 1/2023

Inspec Solutions LLC.