

**DERMA NUMB PAIN RELIEF- lidocaine hcl gel**  
**A.T.S. Laboratories, LLC**

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**Derma Numb Pain Relieving Spray**

**Active Ingredients**

Lidocaine HCL 4.0% w/w

**Purpose**

External Analgesic

**Uses**

For temporary relief of pain and itching associated with minor cuts or minor skin irritations.

**Warnings**

**For external use only**

**Avoid contact with eyes**

**Do not use** in large quantities, particularly over raw surfaces or blistered areas

**Stop use and ask doctor if**

- Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again with a few days. Discontinue use.

**Keep out of reach of children**

- If product is swallowed, get medical help or contact a poison control center right away.

**Directions**

For adults and children two-years or older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a physician.

**Inactive Ingredients**

Achillea Millegolium (Yarrow) Extract, Caprylyl Glycol, Citric Acid, Disodium EDTA, Methylisothiazolinone, Propylene Glycol, Schidigera (Yucca) Root Extract, Sodium Metabisulfate, Water.

**Other Information**

Protect this product from excessive heat and direct sun.

**Questions or Comments?**

954-492-9898

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Lidocaine HCL 4.0% w/w	External Analgesic
<b>Uses</b> For the temporary relief of pain and itching associated with minor cuts or minor skin irritations	
<b>Warnings</b> For external use only Avoid contact with eyes Do not use in large quantities, particularly over raw surfaces or blistered areas Stop use and ask doctor if <ul style="list-style-type: none"> <li>Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days discontinue use.</li> </ul> Keep out of reach of children <ul style="list-style-type: none"> <li>If product is swallowed, get medical help or contact a poison control center right away.</li> </ul>	

Clear Label 3.5" x 1.5"



<b>Drug Facts</b> (continued)	
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<b>Questions or Comments?</b> 954-492-9898	

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# DERMA NUMB PAIN RELIEF

lidocaine hcl gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70188-005
<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	40 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ACHILLEA MILLEFOLIUM</b> (UNII: 2FXJ6SW4PK)	
<b>YUCCA SCHIDIGERA</b> (UNII: 08A0YG3VIC)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70188-005-01	28 g in 1 PACKAGE; Type 0: Not a Combination Product	07/01/2015	
2	NDC:70188-005-04	113 g in 1 PACKAGE; Type 0: Not a Combination Product	07/01/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	07/01/2015	

**Labeler** - A.T.S. Laboratories, LLC (080013331)

## Establishment

Name	Address	ID/FEI	Business Operations
Southeast Holdings Corp		080504027	manufacture(70188-005) , label(70188-005) , pack(70188-005)

