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

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 then 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

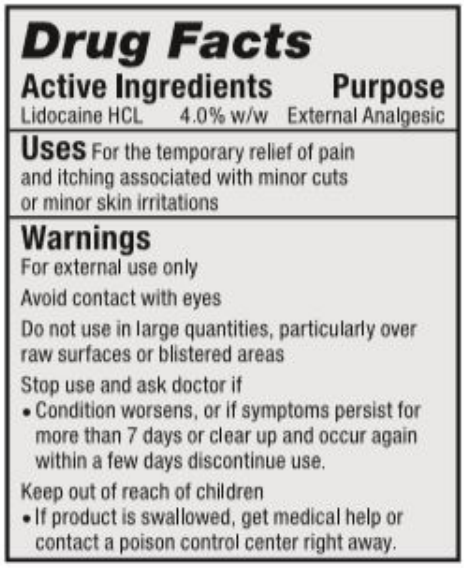
Achillea Millegolium (Yarrow) Extract, Caprylyl Glycol, Citric Acid, Disodium EDTA, Methylisothiazolinone, Propylene Glycol, Schidigera (Yucca) Root Extract, Sodium Metabisulfate, Water.

Other Information

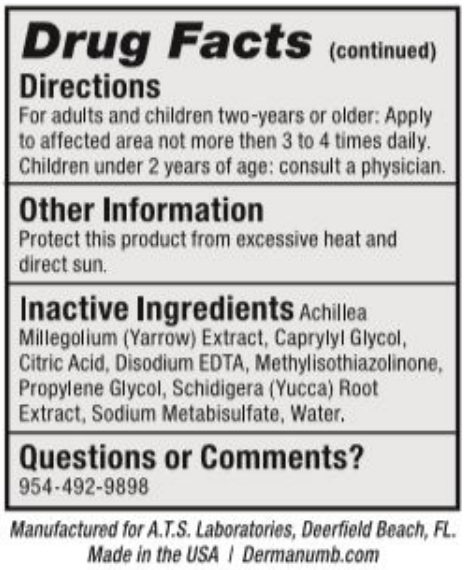
Protect this product from excessive heat and direct sun.

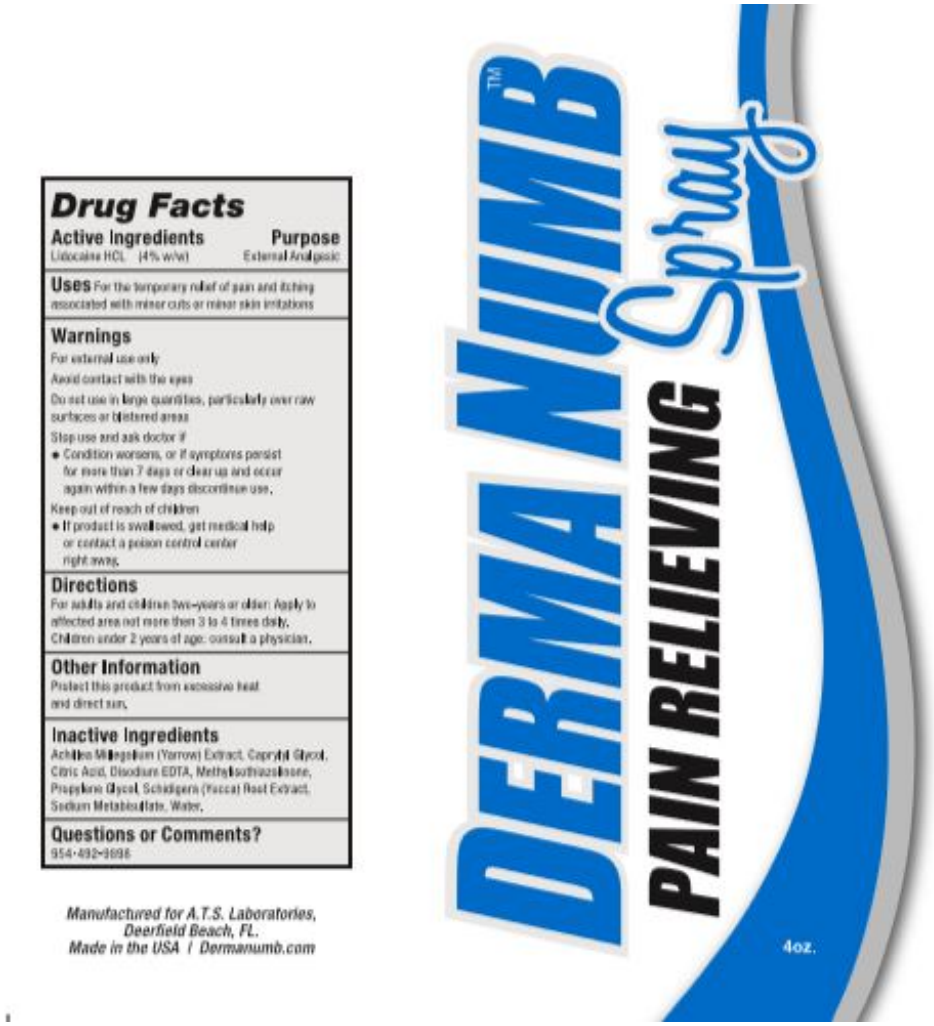
Questions or Comments?

954-492-9898



Clear Label 3.5" x 1.5"





DERMA NUMB PAIN RELIEF

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70188-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)	
YUCCA SCHIDIGERA (UNII: 08A0YG3VIC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (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 not final	part348	07/01/2015	

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

Revised: 1/2022 A.T.S. Laboratories, LLC