

LIDOCOLL - lidocaine hcl spray
Innocoll Pharmaceuticals

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.

Drug Facts

Lidocaine HCl 4%.....Anesthetic

Purpose

Anesthetic

Warning

Keep out of reach of children

Use

For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritations.

Warning

Avoid contact with eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use and consult a doctor. Keep out of reach of children.

Directions

Adults and children 2 years of age and older: Apply Lidocoll spray not more than 3 to 4 times per day or moisten dressing prior to removal to reduce pain.
Children under 2 years of age consult a doctor.

Inactive Ingredients

hydrolyzed fish collagen (15%), purified water, benzethonium chloride and HCl.



LIDOCOLL

lidocaine hcl spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51715-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride	4.6 g in 115 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Benzethonium Chloride (UNII: PH41D05744)	115 mg in 115 g
Hydrochloric Acid (UNII: QTT17582CB)	100 mg in 115 g
Fish (UNII: 1PIO77PW2X)	17.25 g in 115 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51715-001-01	115 g in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2011	

Labeler - Innocoll Pharmaceuticals (989921395)

Revised: 12/2011

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