CUTIECAINE - topical lidocaine (4% w/w) cream Innovatech Inc

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

Cutiecaine, Topical Lidocaine Cream (4% w/w), Active Ingredient; Lidocaine Hydrochloride 4% (w/w), Inactive Ingredients; water, Isoprpopyl Alcohol, gkycerin, Ethyl alcohol, Staeric Acid, Carbomer, Sodium Hyaluronate, castor oil, Innovatech Inc, Net Wt. 15g

Use for reducing pain or discomfort from minor cuts, abrasions, minor burns, sun burns, insect bites, poison ivy, hemorrhoids pain and Itching. Use small amount (1 to 2 gm) of this medication, apply on the skin with gentle massage to numb the skin or relieve pain (do not occlude). Children under 2 years of age, consult your doctor

- Do not use in or near the eyes
- Do use in large amount particularly over the raw surfaces or blisters Stop use and Ask Doctors if
- Allergic reactions occurs
- Condition worsen and does not improve
- Symptoms clean up and returns within few day
- itching, redness, burning, swelling or other symptoms occurs
- Keep both used and unused medicine out of the reach of children or pets
- If swallowed get medical attention right away Call your doctor immediately.

carton.jpg

Carton.jpg

NDC 50876-111-01

Cutiecaine

Rapid Acting Topical Anesthetic Cream

Lidocaine 4% w/w

Innovatech Inc

2002-B Hazel Street Birmingham, MI 48009 (248) 341-3401

Net Wt. 15 g

Label; Drug Facts

Active Ingredient Lidocaine 4% w/w Anesthetic Uses; to reduce pain or discomfort from;

Topical

- minor cuts.
- scratches
- sunburn,
- insect bites,
- · poison ivy,
- poison oak,
- hemorrhoids Pain and Itching
- Minor burns.

Warnings; For external uses only

When using this product;

Do not use in or near the eyes

Do use in large amount particularly over the raw surfaces or blisters

Stop use and Ask Doctors if

Allergic reactions occurs

Condition worsen and does not improve

Symptoms clean up and returns within few day itching, redness, burning, swelling or other symptoms

Keep both used and unused medicine out of the reach of

If swallowed get medical attention right away Call your doctor immediately.

Directions; Use small amount (1 to 2 gm) of this medication, apply on the skin with gentle massage to numb the skin or relieve pain. Children under 2 yearsof age, consult your

Storage; store at room temperature (25°C) and away from

Inactive Ingredients; water, Isoprpopyl Alcohol, gkycerin, Ethyl alcohol, Staeric Acid, Carbomer, Sodium Hyaluronate, castor oil,

Net Weight; 15 g

CUTIECAINE

topical lidocaine (4% w/w) cream

Product Information

HUMAN OTC DRUG NDC:50876-111 Product Type Item Code (Source)

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE -	LIDOCAINE	40 mg in 1 g
UNII:98PI200987)	HYDROCHLORIDE	40 mg in 1 g

Inactive	Ingredien	its
----------	-----------	-----

Ingredient Name	Strength
ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE (UNII: V5VD430 YW9)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CASTOR OIL (UNII: D5340 Y2I9G)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50876-111-02	1 in 1 CARTON		
1 NDC:50876-111-01	15 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/31/2010	

Labeler - Innovatech Inc (833205961)

Registrant - Innovatech Inc (833205961)

Establishment			
Name	Address	ID/FEI	Business Operations
Innovatech Inc		833205961	manufacture, label, analysis, pack

Revised: 5/2010 Innovatech Inc