CUTIECAINE - topical lidocaine (5% w/w) cream Transdermal Corp

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-5%, Topical Lidocaine Cream (5% 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

for relief of pain and discomfort from; hemorrhoids pain and Itching, Other Uses; minor cuts, bruises, sun burn, insect bites, poison ivy, etc.

Use for reducing pain or discomfort from; hemorrhoids pain and Itching. minor cuts, abrasions, minor burns, sun burns, insect bites, poison ivy, 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

Keep both used and unused medicine out of the reach of children or pets

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

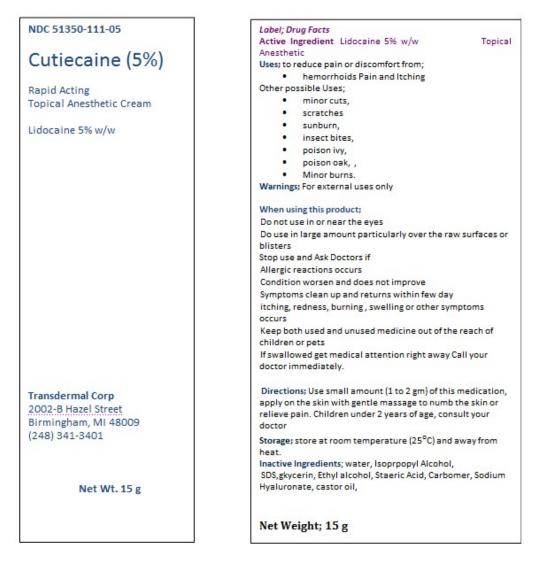
- Do not use in or near the eyes
- Do use in large amount particularly over the raw surfaces or blisters

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.

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Carton.jpg



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CUTIECAINE					
topical lidocaine (5% w/w) cream					
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:51350-111	
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ingr		Basis of Strength		Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)			LIDOCAINE HYDROCHLORIDE		50 mg in 1 g
Inactive Ingredients					
	Ingredient Name			S	trength
WATER (UNII: 0590F0K00R)					

CF	RBOMER HOMOPOL	LYMER TYPE C (UNII: 4Q93RCW27E)		
Gl	YCERIN (UNII: PDC6A	A3C0OX)		
SI	EARIC ACID (UNII: 4E	ELV7Z65AP)		
so	DIUM LAURYL SULI	F ATE (UNII: 368GB5141J)		
IS	OPROPYL ALCOHOI	L (UNII: ND2M416302)		
CI	TYL ALCOHOL (UNI	II: 936JST6JCN)		
AI	COHOL (UNII: 3K995	58 V90 M)		
AI	OE (UNII: V5VD430 YV	W9)		
H	ALURO NATE SO DIU	J M (UNII: YSE9PPT4TH)		
РС	LYSORBATE 20 (UN	NII: 7T1F30V5YH)		
BU	TYLENE GLYCOL (U	JNII: 3XUS85K0RA)		
	TYLENE GLYCOL (U STOR OIL (UNII: D53	,		
CA		,		
C/	STOR OIL (UNII: D53	,	Marketing Start Date	Marketing End Date
C# Pa #	STOR OIL (UNII: D53	340 Y2I9 G)	Marketing Start Date	Marketing End Date

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/15/2011	

Labeler - Transdermal Corp (963383612)

Registrant - Transdermal Corp (963383612)

Establishment

Name	Address	ID/FEI	Business Operations
Transdermal Corp		963383612	manufacture, label, analysis, pack

Revised: 11/2011

Transdermal Corp