

**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.*

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**Drug Facts**

Cutiecaine-5%, Topical Lidocaine Cream (5% w/w), Active Ingredient; Lidocaine Hydrochloride 4% (w/w), Inactive Ingredients; water, Isopropyl Alcohol, glycerin, Ethyl alcohol, Stearic 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, Isopropyl Alcohol, glycerin, Ethyl alcohol, Stearic 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.

carton.jpg

Carton.jpg

NDC 51350-111-05

## Cutiecaine (5%)

Rapid Acting  
Topical Anesthetic Cream

Lidocaine 5% w/w

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

**Net Wt. 15 g**

**Label; Drug Facts**

**Active Ingredient** Lidocaine 5% w/w Topical Anesthetic

**Uses;** to reduce pain or discomfort from;

- hemorrhoids Pain and Itching

**Other possible Uses;**

- minor cuts,
- scratches
- sunburn,
- insect bites,
- poison ivy,
- poison oak, ,
- 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 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.

**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 years of age, consult your doctor

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

**Inactive Ingredients;** water, Isopropyl Alcohol, SDS, glycerin, Ethyl alcohol, Stearic Acid, Carbomer, Sodium Hyaluronate, castor oil,

**Net Weight; 15 g**

## CUTIECAINE

topical lidocaine (5% w/w) cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51350-111
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	50 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

CARBOMER HOMO POLYMER 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: V5VD430YW9)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CASTOR OIL (UNII: D5340Y2I9G)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51350-111-02	1 in 1 CARTON		
1	NDC:51350-111-01	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	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