CURACAINE- lidocaine 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.

Active Ingredients

Lidocaine 4%

PURPOSE:

topical analgesic

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses for the temporary relief of

- pain and itching
- insect bites
- sunburn
- minor cuts
- scrapes
- burns
- minor skin irritations

Warnings

For external use only

When using this product

- Keep out of eyes. Rinse with water to remove.
- Do not use in large quantities, particularly over raw surfaces or blistered areas.
- If pregnant or breast feeding, ask a health professional before use.

Directions

Adults and children 2 years of age and older:

Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: consult a doctor.

Inactive Ingredients

Caprylyl Glycol, Cetearyl Alcohol, Clyclopentasiloxane, Deionized water, Dimethyl Sulone, Glycerin, Hexylene Glycol, Phenoxyethanol, Polysorbate 20, Polysorbate 60, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium hyaluronate, Sodium Lauryl Sulfate, Stearic Acid, Tetrasodium EDTA, Tocopheryl Acetate

Stop use and ask a doctor if conditions worsens, or, if symptoms persist for more than 7 days, or clear up and occur again within a few days, discontinue use of the product and consult a doctor.


NEW!
RELIEVES
ITCHING + PAIN
Scientifically Advanced!
Maximum Strength!
Rapid Acting!
Pain • Itching
Insect Bites
Sunburn
Minor Cuts • Burns
Minor Skin Irritations
POWERED BY ADVANCED TECHNOLOGY!
Relieves Itching + Pain
Contains Maximum Strength Lidocaine 4%
Contains Maximum Strength Lidocaine 4%
NEW!
CURACAINE
RAPID ACTING TOPICAL ANALGESIC
NEW!
Advanced Itching + Pain Relief Formula
Powered By Advanced Technology Lidocaine 4%
Net Wt. 1 fl oz 30ml


NEW!
CURACAINE
Rapid Acting,
Maximum Strength
Pain & Itching Relief!
New and Advanced
Revolutionary Technology
Delivers Curacaine's
4% Lidocaine.
For best
results,
massage
Curacaine to
affected area
for 30 seconds.
Transdermal Corporation
2002 B Hazel St. Birmingham, MI 48009
Made in U.S.A.
Drug Facts
Active Ingredients
Lidocaine..... 4%
Purpose
Topical Analgesic
Uses For the temporary relief of ■ pain and itching ■ insect bites ■ sunburn ■ minor cuts ■ scrapes ■ burns ■ minor skin irritations
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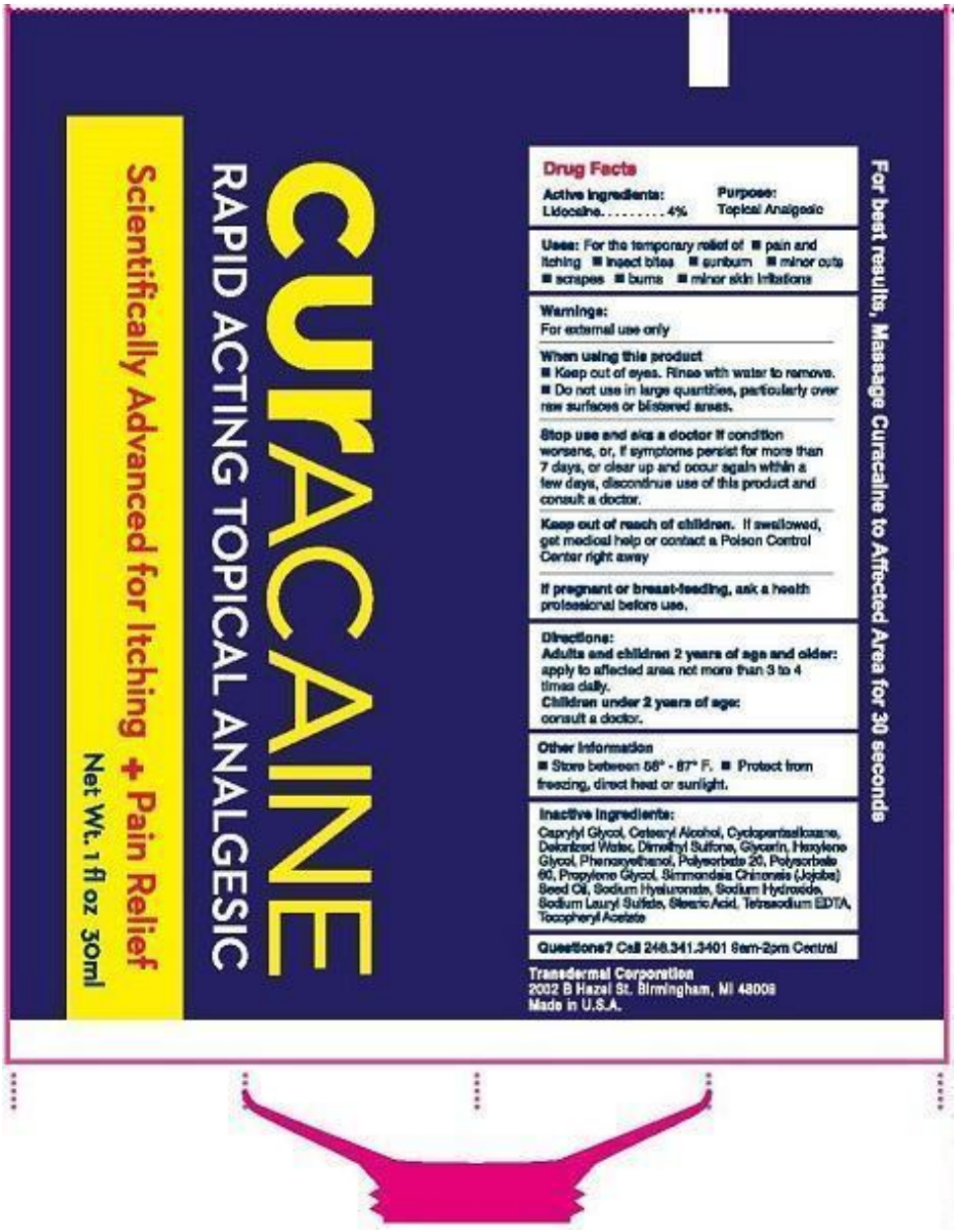
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
If pregnant or breast-feeding, ask a health professional before use.
Directions
Adults and children 2 years of age and older:
apply to affected area not more than 3 to 4 times daily.
Children under 2 years of age: consult a doctor.
Other information ■ Store between 68° - 87° F
■ Protect from freezing, direct heat or sunlight
Inactive Ingredients
Caprylyl Glycol, Cetearyl Alcohol, Cyclopentasiloxane, Deionized Water, Dimethyl Sulone, Glycerin, Hexylene Glycol, Phenoxyethanol, Polysorbate 20, Polysorbate 60, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hyaluronate, Sodium Lauryl Sulfate, Stearic Acid, Tetrasodium EDTA, Tocopheryl Acetate
Questions? Call 248.341.3401 8:00am - 2:00pm Central



CURACAINE

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51350-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
WATER (UNII: 059QF0KO0R)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
JOJOBA OIL (UNII: 724GKU717M)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51350-011-51	1 in 1 BOX		
1	NDC:51350-011-01	30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/03/2015	

Labeler - Transdermal Corp (963383612)

Registrant - Transdermal Corp (963383612)

Revised: 4/2015 Transdermal Corp