

CURACAINE- lidocaine hcl 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 HCL 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, Cetaryl 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 Sulfate, Steric Acid, Tetrasodium EDTA, Tocopheryl Acetate, Sodium Hydroxide.

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.

PURPOSE

TOPICAL ANALGESIC

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.

STOP USE AND ASK A DOCTOR IF CONDITION WORSENS, OR, IF SYMPTOMS PERSIST FOR MORE THAN 7 DAYS, OR CLEAR UP AND OCCUR AGAIN WITHIN A FEW DAYS, DISCONTINUE USE OF THIS PRODUCT AND CONSULT A DOCTOR.

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 58° - 87° F.
- PROTECT FROM FREEZING, DIRECT HEAT OR SUNLIGHT.

QUESTIONS?

CALL 248.341.3401 9AM-2PM CENTRAL

INACTIVE INGREDIENTS:

CAPRYLYL GLYCOL, CETEARYL ALCOHOL, CYCLOPENTASILOXANE, DEIONIZED WATER, DIMETHYL SULFONE, GLYCERIN, HEXYLENE GLYCOL, PHENOXYETHANOL, POLYSORBATE 20, POLYSORBATE 60, PROPYLENE GLYCOL, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, SODIUM HYALURONATE, SODIUM HYDROXIDE, SODIUM LAURYL SULFATE, STEARIC ACID, TETRASODIUM EDTA, TOCOPHERYL ACETATE.

For best results, Massage Curracline to Affected Area for 30 seconds

Drug Facts

Active Ingredients:	Purpose(s)
Lidocaine HCl 4%	Topical Anesthetic

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.

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

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 59° - 87° F. ■ Protect from freezing, direct heat or sunlight.

Inactive Ingredients:
Caprylyl Glycol, Cetearyl Alcohol, Cyclopentasiloxane, Deionized Water, Dimethyl Siloxane, Glycerin, Hydroxyethyl Glycol, Phenoxethanol, Polyorbital 20, Polyorbital 60, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hyaluronate, Sodium Hydroxide, Sodium Lauryl Sulfate, Stearic Acid, Tetracosylum EDTA, Tocopheryl Acetate

Questions? Call 248.541.3401 Pam-Spm Central

Transdermal Corporation
2002 B Hazel St. Birmingham, MI 48009
Made In U.S.A.

CURRACLINE

RAPID ACTING TOPICAL ANALGESIC

Scientifically Advanced for Itching + Pain Relief

Net Wt. 1 fl oz 30ml

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%

CURACAIN

RAPID ACTING TOPICAL ANALGESIC

Advanced Itching + Pain Relief Formula

Powered By Advanced Technology Lidocaine 4%

Net Wt. 1 fl oz 30ml

NEW!

NEW!



Drug Facts

Active Ingredients
Lidocaine Hydrochloride 4%
Topical Analgesic

Purpose
Lidocaine Hydrochloride 4% is used to numb the skin and relieve minor pain and itching.

Warnings
Do not use on large quantities, particularly over raw surfaces or blisters.

Directions
Apply to affected area not more than 2 to 4 times daily. Rub gently. Do not use on large quantities, particularly over raw surfaces or blisters.

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

Questions?
For more information, call 1-800-368-3773 or visit our website at www.curacaine.com.

NEW!

Rapid Acting, Maximum Strength Pain & Itching Relief!

Curacaine to Massage

For best results, Curacaine to affected area for 30 seconds.

New and Advanced Revolutionary Technology Delivers Curacaine's 4% Lidocaine.

Made in U.S.A.

lidocaine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51350-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
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)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51350-012-51	1 in 1 BOX	09/12/2012	
1	NDC:51350-012-11	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	09/12/2012	

Labeler - Transdermal Corp (963383612)

Registrant - Transdermal Corp (963383612)

