LIDOSTAT - lidocaine hcl cream Clinical Therapeutic Solutions

LidoStat CREAM

LidoStat CREAM

Active Ingredient

Lidocaine HCL 4%

Purpose

External Anesthetic

Uses:

For temporary relief of pain and itching caused by minor skin irritations.

Warnings:

For external use only.

Do not use

on children under 2 years of age unless directed by a physician.

When using this product

avoid contact with eyes Use only as directed. Do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if:

- symptoms persist for more than seven days, or clear up and occur again within a few days.
- redness, irritation, swelling, pain or other symptoms increase

Keep out of reach of children.

If swallowed, consult a physician.

Directions:

For adults and children two-years or older, apply externally to the affected area. Do not use more than three to four times per day.

Children under 2 years of age: Ask a doctor.

Other information:

Store at room temperature (68-77°F) (20°-25°C)

Other Ingredients:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Bin Vinyl Dimethicone/Dimethicone Copolymer, C13-14 Isoparaffin, Cetyl Alcohol, Dimethicone, Ethylhexylglycerin, Laureth-7, Methylsulfonylmethane (MSM), Phenoxyethanol, Polyacrylamide, Polysorbate-20, Stearic Acid, Triethanolamine, Urea.

Question or Comments?

Please visit www.BakoCTS.com

LidoStatTM Cream

Distributed by: CLINICAL THERAPEUTIC SOLUTIONS A Part of bako's Integrated Physician Solution PO Box 1257, Wall, NJ 07719 732.894.9450 •

www.BakoCTS.com

LidoStat CREAM

Lidocaine HCI 4% In a 20% Urea Vehicle MEDICAL STRENGTH PAIN CREAM

PENETRATING FORMULA Dipensed Only by Physicians NET WT. 2.0 oz (56 g) LOT: EXP:

LidoStat CREAM 2oz/56g (44577-704-02)

LidoStat[®]

Lidocaine HCI 4% In a 20% Urea Vehicle

MEDICAL STRENGTH PAIN CREAM

PENETRATING FORMULA

Dispensed Only by Physicians



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LidoStat[™] Cream

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-Lidocaine HCl.......4.00% External Anesthetic Uses:

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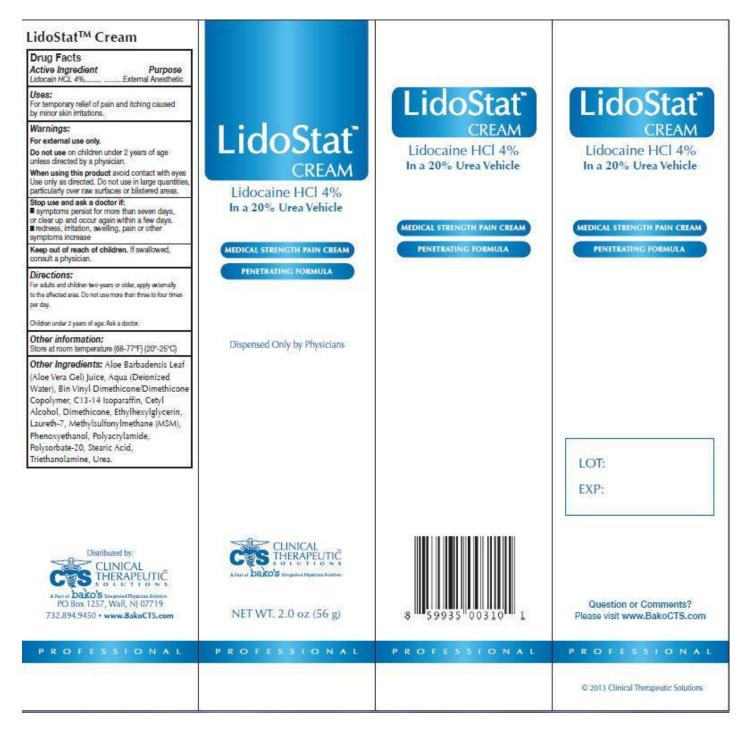
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LIDOSTAT lidocaine hcl cream **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:44577-704 **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE -LIDOCAINE HYDROCHLORIDE 40 mg UNII:98PI200987) ANHYDROUS in 1 g

Inactive Ingredients	
-	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LAURETH-7 (UNII: Z95S6G8201)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	
UREA (UNII: 8W8T17847W)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:44577-704- 02	1 in 1 CARTON	02/07/2017				
1		56 g in 1 TUBE; Type 0: Not a Combination Product					
Marketing Information							

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M017	06/19/2013	

Labeler - Clinical Therapeutic Solutions (078402750)

Revised: 11/2023

Clinical Therapeutic Solutions