PAIN RELIEF- lidocaine hcl cream Topco

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

Active ingredient

Purpose

Lidocaine HCl 4%

Topical Analgesic

Uses

Uses For temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritation

Warnings

IFor external use only

When using this product • avoid contact with eyes • do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of the children.

If product is swallowed, get medical help or contact a Poison Control Center right away

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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, C30-45 Alkyl Cetearyl Dimethicone, Crosspolymer, Caprylyl Methicone, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicetyl Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl Stearate, Methylparaben, SD Alcohol 40, Steareth-21, Water

TopCare



Pain Relieving Topical Analgesic

- No irritation
- No burning
- Non-greasy

FopCare

MAXIMUM STRENGTH · ODOR FREE

Pain Relief Cream

LIDOCAINE HCI 4%/Topical Analgesic For the temporary relief of pain and itching

TopCare.
Pain Relief
Cream

LIDOCAINE HCI 4%





NET WT 2.7 OZ (76.5 g)



DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com



Drug Facts

Active ingredient

Purpose

Lidocaine HCI 4%...

.Topical analgesic

Uses

Temporarily relieves pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritation.

Warnings

For external use only.

When using this product • avoid contact with eyes • 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 immediately.

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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Caprylyl Methicone, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicetyl Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl Stearate, Methylparaben, SD Alcohol 40, Steareth-21, Water.

ACTUAL SIZE

PAIN RELIEF

lidocaine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-740
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
Ceteth-20 Phosphate (UNII: 921FTA1500)			
DIHEXADECYL PHO SPHATE (UNII: 2V6E5WN99N)			
Dimethicone (UNII: 92RU3N3Y1O)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
Ethylhexylglycerin (UNII: 147D247K3P)			
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)			

^{*}This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Aspercreme®.

Methylparaben (UNII: A218 C7H19T)			
ALCOHOL (UNII: 3K9958V90M)			
Steareth-21 (UNII: 53J3F32P58)			
Water (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-740-03	77 g in 1 CONTAINER; Type 0: Not a Combination Product	11/17/2017	
Marketing Information				
I	Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ОТ	TC monograph not fin	al part348	11/17/20 17	

Labeler - Topco (006935977)

Registrant - Product Quest Mfg. (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg.		927768135	manufacture(36800-740), label(36800-740)	

Revised: 7/2018 Topco