TOPCARE COLD AND HOT PAIN RELIEVING ANALGESIC- lidocaine hydrochloride and menthol, unspecified form cream Topco Associates, LLC

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.

TopCare® Cold & Hot Pain Relieving Cream Topical Analgesic

Drug Facts

Active ingredients	Purpose	
Lidocaine HCl 4%	Topical analgesic	
Menthol 1%	Topical analgesic	

Use

temporarily relieves minor pain

Warnings

For external use only

Do not use

- ◆ on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- ◆ for more than one week without consulting a doctor

When using this product

- use only as directed. Read and follow all directions and warnings on this carton
- rare cases of serious burns have been reported with products of this type
- do not bandage or apply local heat (such as heating pads) to the area of use with a medicated patch
- avoid contact with eyes and mucous membranes
- a transient burning sensation may occur upon application but generally disappears in several days

Discontinue use and consult a doctor if

- condition worsens
- redness is present
- irritation develops

- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

Adults and children over 12 years:

- ◆ Apply to affected area not more than 3 to 4 times daily
- **♦ AFTER APPLYING, WASH HANDS WITH SOAP AND WATER**

children under 12 years or younger: ask a doctor

Other information

store at room temperature

Inactive ingredients

acrylates/C10-30 alkyl Acrylate crosspolymer, alcohol denat., aloe barbadensis leaf juice, aminomethyl propanol, C30-45 alkyl cetearyl dimethicone crosspolymer, caprylyl methicone, cetearyl alcohol, ceteth-20 phosphate, dicetyl phosphate, dimethicone, disodium EDTA, ethylhexylglycerin, glyceryl stearate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isohexadecane, phenoxyethanol, polysorbate 60, steareth-21, water.

Questions or comments?

1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 77 g Bottle Carton

TopCare_® health

COMPARE TO ICY HOT® ACTIVE INGREDIENTS*

MAXIMUM STRENGTH LIDOCAINE

Cold & Hot Pain Relieving Lidocaine Cream 4% Lidocaine • 1% Menthol

LIDOCAINE 4% / TOPICAL ANALGESIC MENTHOL 1% / TOPICAL ANALGESIC

- Helps to Numb Away Pain
- Non-Greasy
- Maximum Strength External Analgesic with 4% Lidocaine

NET WT 2.7 OZ (77 g)



MAXIMUM STRENGTH LIDOCAINE

Cold & Hot

Pain Relieving Lidocaine Cream

4% Lidocaine • 1% Menthol



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MAXIMUM STRENGTH LIDOCAINE

Cold & Hot

Pain Relieving Lidocaine Cream

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LIDOCAINE 4% / TOPICAL ANALGESIC MENTHOL 1% / TOPICAL ANALGESIC

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- · Non-Greasy
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MAXIMUM STRENGTH LIDOCAINE

Cold & Hot

Pain Relieving Lidocaine Cream

4% Lidocaine • 1% Menthol

LIDOCAINE 4% / TOPICAL ANALGESIC MENTHOL 1% / TOPICAL ANALGESIC

- Helps to Numb Away Pain
- Non-Greasy
- Maximum Strength External Analgesic with 4% Lidocaine

NET WT 2.7 OZ (77 g)

07-256



COMPARE TO ICY HOT® ACTIVE INGREDIENTS*

MAXIMUM STRENGTH LIDOCAINE

Cold & Hot

Pain Relieving Lidocaine Cream

4% Lidocaine • 1% Menthol

TEMPORARILY RELIEVES MINOR PAIN FOR:

Back, Neck & Shoulder Knee Elbow







Foot, Ankle & Lea





Drug Facts

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Menthol 1%	Topical analgesic

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Warnings

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(Questions or comments? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 ©TOPCO GLBA0322 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com MADE IN CANADA

*This product is not manufactured or distributed by CHATTEM, INC., owner of the registered trademark Icy Hot ®.

Keep carton as it contains important information. Close cap tightly between uses. Child resistant packaging.



Scan here for more information or call 1-888-423-0139

TOPCARE COLD AND HOT PAIN RELIEVING ANALGESIC

lidocaine hydrochloride and menthol, unspecified form cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76162-180

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1 g		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 g		

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
C30-45 Alkyl Cetearyl Dimethicone Crosspolymer (UNII: 4Z K9VP326R)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Ceteth-20 Phosphate (UNII: 921FTA1500)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
Dimethicone (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Ethylhexylglycerin (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
Isohexadecane (UNII: 918X1OUF1E)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Steareth-21 (UNII: 53J3F32P58)	
Water (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:76162-180- 01	1 in 1 CARTON	05/24/2022		
1		77 g in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Marketing Start Citation Date		Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	05/24/2022	

Labeler - Topco Associates, LLC (006935977)

Registrant - Garcoa, Inc. (036464697)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sigan Industries INC.		255106239	MANUFACTURE(76162-180)	

Revised: 8/2022 Topco Associates, LLC