

HOT AND COLD WITH LIDOCAINE-CAREONE PAIN RELIEVING- lidocaine hcl and menthol cream

SOTAC PHARMACEUTICALS PRIVATE LIMITED

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.

Hot and Cold Cream with Lidocaine- CareOne

Drug Facts

HOT AND COLD CREAM with LIDOCAINE-RA
PAIN RELIEVING CREAM

Drug Facts

Active Ingredients

Lidocaine HCl 4%

Menthol 1%

Purposes

Lidocaine- Topical anesthetic,

Menthol- Topical Analgesic

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 SECTION

- Use only as directed. Read and follow all directions and warnings on this label
- rare cases of serious burns have been reported with products of this type
- do not bandage tightly or apply local heat (such as heating pads) to the area of use or 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

If pregnant or breast-feeding,

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN SECTION

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

DOSAGE & ADMINISTRATION

adults and children over 12 years:

- apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period
- AFTER APPLYING, WASH HANDS WITH SOAP AND WATER

children 12 years or younger: ask a doctor

INACTIVE INGREDIENT SECTION

Butylated hydroxyl toluene, cetostearyl alcohol, cetomacrogol 1000, cetyl alcohol, disodium EDTA, disodium hydrogen phosphate, light liquid paraffin, propylene glycol, sorbic acid, transquitol P, white petroleum jelly


Keep Carton As It Contains Important Information

Close cap tightly between uses.

Outer Label

Temporarily relieves minor pain

Outer Label

CareOne Cold & Hot Pain Relieving Cream 2.7 Oz			
Active Ingredient			
Lidocaine HCl 4%.....		Topical Anesthetic	
Menthol 1%.....		Topical Analgesic	
BATCH NO.		QUANTITY	32x4(x76.5 g) = 128 Bottles
MFG. DATE	05/2018	SHIPPER NO.	of 11
EXP. DATE	04/2020	GROSS WT.	kg.
		NET WT.	9.80 kg.
WARNING: KEEP OUT OF REACH OF CHILDREN AND PETS. FOR EXTERNAL USE ONLY.		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86° F (15 to 30 °C)	
CONFORMANCE WITH THE F.D & C ACT AND REGULATIONS THERE UNDER		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: SOTAC PHARMACEUTICALS PVT LTD PLOT NO. PF-21, SANAND GIDC-II, CHARAL INDUSTRIAL ESTATE, TALUKA-SANAND, DISTRICT-AHMEDABAD 382 110. INDIA			
Lic#GUJ/DRUGS/G/25/2169			
SHIPPED TO: VELOCITY PHARMA LLC 226/B SHERWOOD AVE, FARMINGDALE , NY-11735			
NDC No	76168-204-30		
Barcode No.			
	0 41520 11264 4		

HOT AND COLD WITH LIDOCAINE-CAREONE PAIN RELIEVING

lidocaine hcl and menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72351-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.4 in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-2 (UNII: 7H8VAM7778)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBIC ACID (UNII: X045WJ989B)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72351-005-00	128 in 1 CASE	05/31/2018	
1		76.5 g in 1 BOTTLE; 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	05/31/2018	

Labeler - SOTAC PHARMACEUTICALS PRIVATE LIMITED (876894019)

Revised: 5/2018

SOTAC PHARMACEUTICALS PRIVATE LIMITED