

**HOT AND COLD WITH LIDOCAINE 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.*

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**Hot and Cold Cream with Lidocaine- Bulk- DG**

**Drug Facts**

***HOT AND COLD CREAM with LIDOCAINE***

***PAIN RELIEVING CREAM***

***Drug Facts***

***Active Ingredients***

Lidocaine HCl 4%

Menthol 1%

***Purposes***

Lidocaine- Topical anesthetic,

Menthol- Topical Analgesic

**Uses**

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 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

**Stop use and ask 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 and pets.**

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

***Directions***

**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 ingredients***

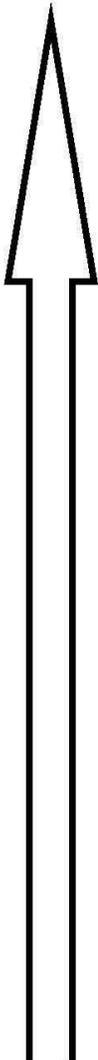
Butylated hydroxyl toluene, cetostearyl alcohol, cetomacrogol 1000, cetyl alcohol, disodium EDTA, disodium hydrogen phosphate, light liquid paraffin, propylene glycol, sorbic acid, transquitol P, white petroleum jelly

**Keep Carton As It Contains Important Information**

**Close cap tightly between uses.**

**Outer Label**

<b>DG Hot `n Cold Pain Relieving Cream 1.75 OZ</b>			
<b>Active Ingredient</b>			
Lidocaine HCl 4%.....		Topical Anesthetic	
Menthol 1%.....		Topical Analgesic	
BATCH NO.	18	QUANTITY	32 x 4 (x 49.6 g) = 132 Bottles
MFG.DATE	04/2018	SHIPPER NO.	out of 46
EXP. DATE	03/2020	GROSS WT.	9.68 kg.
		NET WT.	6.54 kg.
<b>WARNING:</b> 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	
<b>MANUFACTURED BY:</b> 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			
<b>SHIPPED TO:</b> VELOCITY PHARMA LLC 226/B SHERWOOD AVE, FARMINGDALE , NY-11735			
NDC No	76168-450-31		
Barcode No.	 3 76168 40031 1		



<b>HOT AND COLD WITH LIDOCAINE PAIN RELIEVING</b>			
lidocaine hcl and menthol cream			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72351-002
Route of Administration	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.4 g in 1 g
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-2 (UNII: 7H8VAM7778)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
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:72351-002-00	132 in 1 CASE	03/02/2017	
1		49.6 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	03/02/2017	

**Labeler** - SOTAC PHARMACEUTICALS PRIVATE LIMITED (876894019)

Revised: 7/2018

SOTAC PHARMACEUTICALS PRIVATE LIMITED