

**HOT AND COLD CREAM WITH LIDOCAINE- RA PAIN RELIEVING- lidocaine hcl  
and menthol cream  
Velocity Pharma 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.*

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**Hot and Cold Pain Relieving 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

**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.**

**PRINCIPAL DISPLAY PANEL**

Hot and cold Cream -CareOne

Net Wt 2.7 OZ (76.5 g)





**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETETH-2</b> (UNII: 7H8VAM7778)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-200-30	1 in 1 CARTON	09/14/2017	
1		76.5 g in 1 TUBE; 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	09/14/2017	

**Labeler** - Velocity Pharma LLC (962198409)

**Registrant** - Velocity Pharma LLC (962198409)