

# **HOT AND COLD LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF- lidocaine and menthol patch**

**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 Lidocaine with Menthol Patch**

### ***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Lidocaine 4 %	Topical analgesic
Menthol 1%	Topical analgesic

### **Uses**

Temporarily relieves minor pain associated with: arthritis, simple backache, bursitis, tendonitis, muscle strains, sprains & bruises.

### **Warnings**

**For external use only.**

**Do not use if you are allergic or sensitive to lidocaine or menthol. Do not use if pouch is damaged or opened.**

### **When using this product**

- use only as directed
- avoid contact with eyes or mucous membranes
- do not apply to open wounds or sensitive skin
- do not bandage tightly or use a heating pad

### **Stop use and ask a doctor if**

- excessive redness or irritation is present
- condition worsens
- pain persists for more than 7 days
- symptoms clear up and occur again within a few days

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 right away.

### **Directions**

- adults: apply patch to affected area for a maximum of 12 hours. Do not use more than 1 patch every 24 hours.
- children: consult your physician
- remove protective film, gently apply to affected area.

### **Inactive Ingredients**

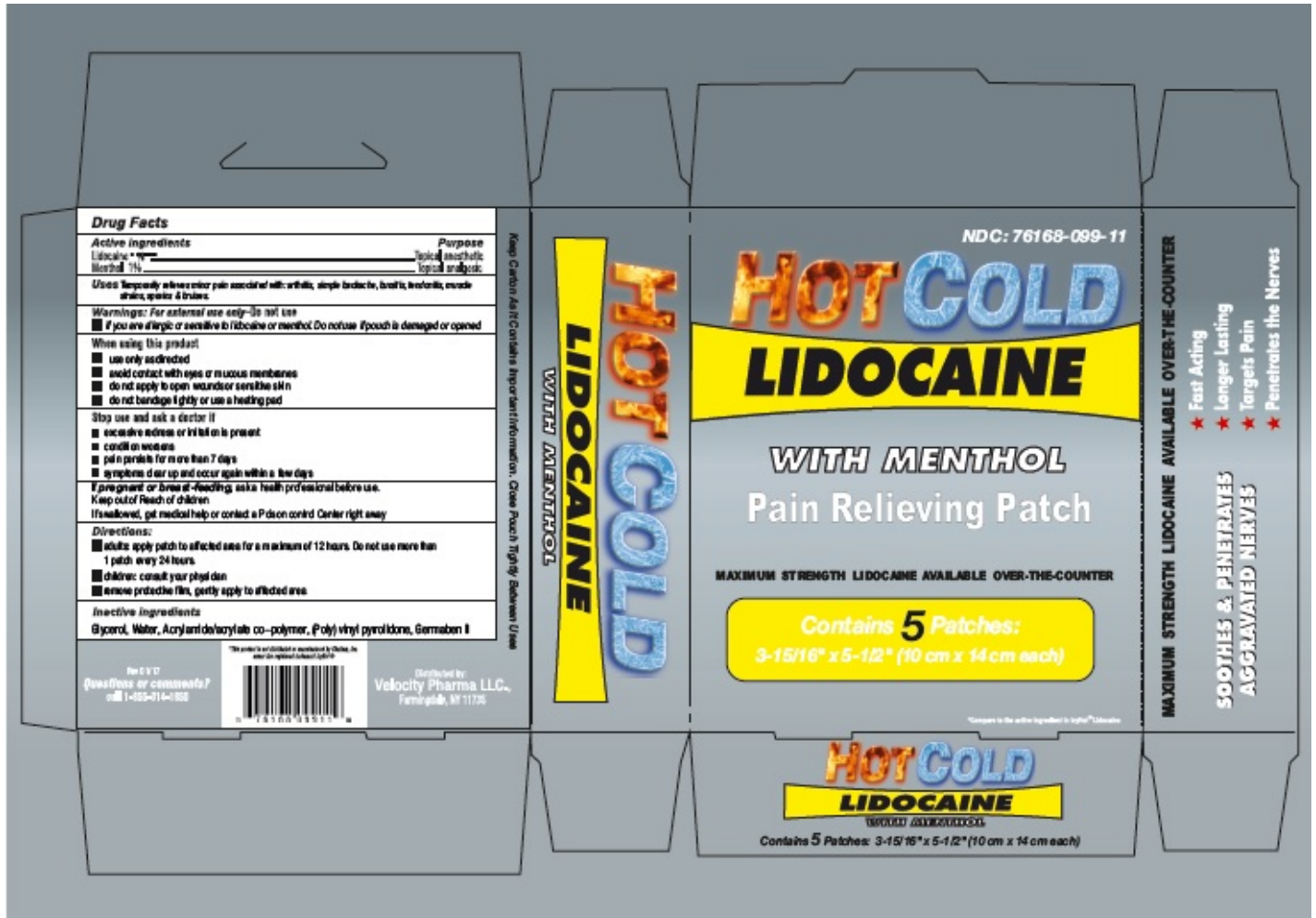
aluminium hydroxide gel, bentonite, borax, carbomer, carboxymethylcellulose sodium, colloidal silicon dioxide, dihydroxyaluminumaminoacetate, disodiumedetate, gelatin, glycerin, oleic acid, polysorbate 80, polyvinyl Alcohol, potassium Sorbate, povidone, propylene glycol, sodiummetabisulphite, tartaric acid, trolamine, urea, water

## PRINCIPAL DISPLAY PANEL - 3 Topical Patch Carton

CONTAINS LIDOCAINE with Menthol

PAIN RELIEF PATCH

5 TOPICAL PATCHES PER BOX



## HOT AND COLD LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF

lidocaine and menthol patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76168-099
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg

MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)

MENTHOL

10 mg

### Inactive Ingredients

Ingredient Name	Strength
ALGELDRATE (UNII: 03J11K103C)	
BENTONITE (UNII: A3N5ZCN45C)	
SODIUM BORATE (UNII: 91MBZ8HBQO)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIHYDROXYALUMINUM AMINO ACETATE (UNII: DO250MG0W6)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLEIC ACID (UNII: 2UMI9U37CP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TARTARIC ACID (UNII: W48881119H)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-099-11	5 in 1 CARTON	03/03/2017	
1		1 in 1 POUCH; 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	03/03/2017	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
DR SABHARWALS WOUND CARE		862184668	manufacture(76168-099)

