

**CVS COLD AND HOT- lidocaine, menthol patch**  
**NATURAL ESSENTIALS, INC.**

*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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**Drug Facts**

**Active ingredients**

Lidocaine 4%

Menthol 1%

**Purpose**

Topical Anesthetic

Topical Analgesic

**Use**

For the temporary relief of pain.

**Warnings**

**For external use only**

**Do not use**

- more than 1 patch on your body at a time 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 apply to wounds or damaged, broken or irritated skin
- Do not allow contact with the eyes and mucous membranes
- Do not bandage tightly or apply local heat (such as heating pads) to the area of use
- Do not use at the same time as other topical analgesics
- Dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug products that can produce serious adverse effects if a child or pet chews or ingests this patch

**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 physician before use.

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

### **Directions**

- **Adults/children 12 years and older**
- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- use 1 patch for up to 12 hours

**Children 12 years or younger:** ask a doctor

### **Other information**

Store at room temperature – do not exceed 86° Fahrenheit, 30° Celsius.

### **Inactive ingredients**

Benzyl Alcohol, Carboxymethylcellulose Sodium, Dihydroxyaluminium Aminoacetate, Ethanol, Glycerin, Kaolin, Partially Neutralized Polyacrylate, Propylene Glycol, Polysorbate 80, Polyvinyl Pyrrolidone 90, Tartaric Acid , Tetrasodium Edetate, Titanium Dioxide, Urea, Water.

### **Principal Display Panel - Cold and Hot Patch Box Label**

NDC 66902-218-05

MAXIMUM STRENGTH

LIDOCAINE

#### **Cold & Hot Patch**

UP TO

12

HOURS

MEDICATED PAIN RELIEF

WITH MENTHOL

LIDOCAINE 4%

MENTHOL 1%

- Desensitizes aggravated nerves
- Easy to apply
- Fast acting

Topical Anesthetic

Topical Analgesic

Package Contains 5 individually

wrapped Patches

5 PATCHES

3 5/16" x 5 1/2" (10 cm x 14 cm)



## Principal Display Panel - Cold and Hot Patch Label

CVS  
Health™

Compare to the active ingredients  
in IcyHot® Lidocaine Patch  
Plus Menthol\*

NDC 66902-218-05

MAXIMUM STRENGTH  
LIDOCAINE

**Cold & Hot  
Patch**

MEDICATED PAIN RELIEF  
WITH MENTHOL

LIDOCAINE 4%

MENTHOL 1%

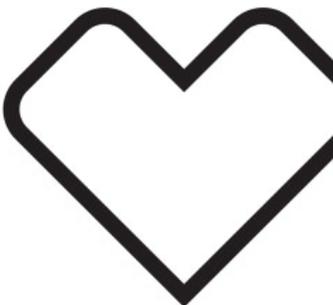
- Desensitizes aggravated nerves
- Easy to apply
- Fast acting

**Topical Anesthetic**

# Topical Analgesic

1 PATCH

3 5/16" x 5 1/2" (10 cm x 14 cm)

<p style="text-align: center; font-size: small;">CUT HERE</p> <div style="display: flex; justify-content: space-between;">  <p>Compare to the active ingredients in IcyHot® Lidocaine Patch Plus Menthol*</p> </div> <p style="text-align: right; font-size: small;">NDC 66902-218-05</p> <p><b>MAXIMUM STRENGTH LIDOCAINE</b></p> <h2 style="margin: 0;">Cold &amp; Hot Patch</h2> <p><b>MEDICATED PAIN RELIEF WITH MENTHOL</b></p> <p><b>LIDOCAINE 4% MENTHOL 1%</b></p> <ul style="list-style-type: none"> <li>• Desensitizes aggravated nerves</li> <li>• Easy to apply</li> <li>• Fast acting</li> </ul> <p><b>Topical Anesthetic Topical Analgesic</b></p> <div style="text-align: center; margin: 20px 0;">  </div> <p><b>1 PATCH</b> 3 5/16" x 5 1/2" (10 cm x 14 cm)</p>	<p style="text-align: center; font-size: small;">CUT HERE</p> <div style="display: flex; justify-content: space-between;">  </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p><b>Drug Facts</b></p> <table style="width: 100%; border-collapse: collapse; font-size: x-small;"> <tr> <th style="text-align: left;">Active ingredients</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Lidocaine 4% .....</td> <td>Topical Anesthetic</td> </tr> <tr> <td>Menthol 1% .....</td> <td>Topical Analgesic</td> </tr> </table> <p><b>Use</b> For the temporary relief of pain.</p> <p><b>Warnings</b> For external use only</p> <p><b>Do not use</b> ■ more than 1 patch on your body at a time or on cut, irritated or swollen skin ■ on puncture wounds ■ for more than one week without consulting a doctor</p> <p><b>When using this product</b> ■ 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 apply to wounds or damaged, broken or irritated skin ■ Do not allow contact with the eyes and mucous membranes ■ Do not bandage tightly or apply local heat (such as heating pads) to the area of use ■ Do not use at the same time as other topical analgesics ■ Dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug products that can produce serious adverse effects if a child or pet chews or ingests this patch</p> <p><b>Stop use and ask a doctor if</b> ■ 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</p> <p><b>If pregnant or breast feeding</b> ask a physician before use. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> ■ <b>Adults/children 12 years and older</b> ■ clean and dry affected area ■ remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle ■ carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area ■ once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area ■ use 1 patch for up to 12 hours <b>Children 12 years or younger:</b> ask a doctor</p> <p><b>Other information</b> Store at room temperature – do not exceed 86° Fahrenheit, 30° Celsius.</p> <p><b>Inactive ingredients</b> Benzyl Alcohol, Carboxymethylcellulose Sodium, Dihydroxyaluminum Aminoacetate, Ethanol, Glycerin, Kaolin, Partially Neutralized Polyacrylate, Propylene Glycol, Polysorbate 80, Polyvinyl Pyrrolidone 90, Tartaric Acid, Tetrasodium Edetate, Titanium Dioxide, Urea, Water.</p> </div> <div style="margin-top: 10px; font-size: x-small;"> <p><b>Distributed by: CVS Pharmacy, Inc.</b> *This product is not manufactured or distributed by Chatham, Inc., owner of the registered trademark IcyHot®. One CVS Drive, Woonsocket, RI 02895 © 2017 CVS/pharmacy CVS.com® 1-800-SHOP CVS</p> <p>Made in China V-33548 </p> </div>	Active ingredients	Purpose	Lidocaine 4% .....	Topical Anesthetic	Menthol 1% .....	Topical Analgesic
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## CVS COLD AND HOT

lidocaine, menthol patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66902-218
<b>Route of Administration</b>	TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

<b>DIHYDROXYALUMINUM AMINOACETATE</b> (UNII: DO250MG0W6)
<b>ALCOHOL</b> (UNII: 3K9958V90M)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>KAOLIN</b> (UNII: 24H4NWX5CO)
<b>POLYACRYLIC ACID (8000 MW)</b> (UNII: 73861X4K5F)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)
<b>TARTARIC ACID</b> (UNII: W4888I119H)
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>UREA</b> (UNII: 8W8T17847W)
<b>WATER</b> (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-218-05	5 in 1 BOX	12/01/2017	
1		1 in 1 PATCH; 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	12/01/2017	

**Labeler** - NATURAL ESSENTIALS, INC. (947484713)

### Establishment

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-218)

Revised: 5/2018

NATURAL ESSENTIALS, INC.