

**SOOTHEE PATCH - lidocaine, menthol, capsaicin, methyl salicylate patch**  
**Better Pain Solutions, LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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**Drug Facts**

**ACTIVE INGREDIENTS:**

Lidocaine	0.5%	External Analgesic
Menthol	5%	External Analgesic/Counterirritant
Capsaicin	0.0375%	External Analgesic
Methyl Salicylate	2%	External Analgesic

**USES:**

Use for temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, sprains, muscle soreness and stiffness

**WARNINGS:**

- For external use only. Use only as directed. Avoid contact with eyes and mucus membranes
- Do not use on wounds or damaged skin
- Stop use and ask a doctor if symptoms persist for more than seven days or clear up and occur again within a few days, or rashes, itching or excessive skin irritation occurs
- Do not cover with bandage
- Do not use if you are allergic to Menthol or Capsaicin
- Consult physician for children under 12

**DIRECTIONS:**

- Adults and children 12 years and over apply to affected area; change patch 2 to 3 times daily
- Children under 12 years, consult a physician before use
- How to apply:
  - Clean and dry affected area
  - Cut open pouch and remove patch
  - If desired, cut patch to size
  - Remove protective film and apply directly to area of pain
  - Apply to affected area not more than 3 times daily
  - Wash hands with soap after applying patch
  - Reseal pouch containing unused patches

**INACTIVE INGREDIENTS:**

Water, Glycerine, Sodium Polyacrylate, Polysorbate 80, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt, Diazolidinyl Urea, Methylparaben, Iodopropynyl Butylcabamate, Propylparaben

Store below 77F (25C)

Avoid direct sunlight

## **Soothee Patch**

### **Better-Rx Manufacturing**

The potential exists for a small child or pet to suffer serious effect from chewing or ingesting a new or used Soothee Patch, although the risk with this formulation has not been evaluated.

It is important for patients to store and dispose of **Soothee Patch** out of the reach of children, pets and others. (See HANDLING AND DISPOSAL)

### **Excessive Dosing**

Excessive Dosing by applying Soothee Patch to larger areas for longer than recommended wearing time could result in increased absorption and higher blood concentrations. Longer duration of application, application of more than the recommended number of patches, smaller patients, or impaired elimination may all contribute to increasing the blood concentration.

## **PRECAUTIONS**

### **General**

#### **Allergic Reactions**

Patients allergic to menthol or capsaicin or any other ingredient in **Soothee Patch** should not use the **Soothee Patch**.

#### **Non-intact Skin**

Application to broken or inflamed skin, although not tested, may result in higher blood concentrations from increased absorption.

#### **Eye Exposure**

The contact of **Soothee Patch** with eyes, although not studied, should be avoided based on the findings of severe eye irritations with the use of similar products in animals. If eye contact occurs, immediately wash out the eye with water or saline.

#### **Pregnancy**

#### **Nursing Mothers**

**Soothee Patch** has not been studied in nursing mothers.

Caution should be exercised when administering the Soothee Patch to nursing mothers. When **soothee patch** is used concurrently with other products in the same class

#### **Pediatric Use**

**Soothee Patch** Safety and effectiveness has not been established in pediatric patients.

## **DOSAGE AND ADMINISTRATION**

Apply **Soothee Patch** to intact skin to cover the area most sensitive to pain. Apply up to four (4) patches per day. Each patch should not be applied for more than 8 hours in a given 24-hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. Clothing may be worn over the area of application. Smaller areas of treatment are recommended in a debilitated patient, or patient with impaired elimination. If irritation or a burning sensation occurs during application, remove the patch and do not reapply until the irritation subsides. When **Soothee Patch** is used concomitantly with other products containing same or similar agents, the amount absorbed from all formulations must be considered.

#### **HANDLING AND DISPOSAL**

Hands should be washed after handling **Soothee Patch**, and eye contact with **Soothee Patch** should be avoided. Do not store patch outside the sealed envelope. Apply immediately after removal from the protective envelope. Fold use patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them. **Soothee Patch** should be kept out of reach of children.

#### **HOW SUPPLIED**

**Soothee Patch** (Lidocaine 0.5%/Menthol 5%/Capsaicin 0.0375%/Methyl Salicylate 2%) is available as the following:  
Box of 15 patches, packaged into 3 child-resistant envelopes (5 patches /envelope)

#### **Patient Information**

**Soothee Patch** is dispensed by prescription (Rx) under medical supervision and direction  
Product Code: **69592-001-01**

Better-Rx Manufacturing does not represent this product code to be a National Drug Codes (NDC). Product Codes are formatted according to standard industry practice, to meet the formatting requirements of pharmacy and health insurance computer systems.

**Store below 77F (25C);** excursion permitted to 59-85F (15-30C) See USP Controlled Room Temperature.

#### **Manufactured for:**

#### **Better-Rx Manufacturing**

**122 E Rose Lane No.C Houston Tx 77076**

For questions or comments please call 1-800-311-6046

March 2015

# Soothee Patch

Rx

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Manufactured For: Better-Rx Manufacturing  
122 E Rose Lane #C Houston, Tx 77076  
For questions or comments please call 1-800-311-6046

Lot No: 150206  
Mfg Date:2/06/2015  
Exp Date:2/05/2018

Made in China – Patent Pending

# Soothee Patch

Qty 15 patches

NDC 69592-001-01

(Lidocaine 0.5% Menthol 5% Capsaicin 0.0375 %, Methyl Salicylate 2%)

# Soothee Patch

# Soothee Patch

21.5x3.5x18.5cm

## SOOTHEE PATCH

lidocaine, menthol, capsaicin, methyl salicylate patch

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69592-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.5 mg in 10 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg in 10 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0375 g in 10 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	2 g in 10 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A218C7H19T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69592-001-01	15 in 1 BOX		
1		10 g in 1 PATCH		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/16/2014	

**Labeler** - Better Pain Solutions, LLC (079703680)

Revised: 3/2015

Better Pain Solutions, LLC