

**PURE-AID- lidocaine, menthol patch**  
**Kareway Product, 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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**Lidocaine Plus Menthol Patch**

**Active ingredient**

Lidocaine 4%

Menthol 1%

**Purposes**

Topical Anesthetic

Topical Analgesic

**Uses**

Temporarily relieves minor 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 label.
- 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 product 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 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:**

- 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 2 patch for up to 24 hours

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

### **Inactive Ingredients**

dihydroxyaluminum aminoacetate, glycerol, kaolin, methylparaben, polyacrylic acid, propylene glycol, propylparaben, pvp, sodium polyacrylate, tartaric acid, titanium dioxide, tween 80, water

### **Package/Label Principal Display Panel**

#### **Pure-Aid**

#### **MAXIMUM STRENGTH**

#### **LIDOCAINE PATCH**

#### **PLUS MENTHOL**

Targeted Immediate Pain Relief

- Desensitizes Aggravated Nerves
- Dual Action with Lidocaine and Menthol
- Fast Acting and Long Lasting
- First Aid for Pain

Pain Relieving Ointment

on a Breathable Adhesive Pad

Contains 1 Patch

3-15/16" x 5-1/2" (10 cm x 14 cm) each

### **Label**

**Drug Facts**

<b>Active Ingredient</b>	<b>Purpose</b>
Lidocaine 4% Menthol 1%	Topical Anesthetic Topical Analgesic

**Uses** Temporarily relieves minor pain

**Warnings** For external use only.

**Do not use if pouch is damaged or opened.**

**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 pouch
- 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 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:** • Clean and dry affected area • Carefully remove backing film from patch  
• Apply one patch to affected area • Do not use more than 2 patches in 24 hours unless, directed by a doctor.

**Children under 12 years:** ask a doctor.

**How to apply**

- Remove backing from patch by firmly grasping both ends and gently pull backing to separate it in middle.
- Carefully remove one portion of backing from patch and apply exposed portion of patch to affected area.
- Once exposed portion of patch is positioned, remove remaining backing to completely apply patch to affected area.

**Inactive Ingredients**  
dihydroxyaluminum aminoacetate, glycerol, kaolin, methylparaben, polyacrylic acid, propylene glycol, propylparaben, pvp, sodium polyacrylate, tartaric acid, titanium dioxide, tween 80, water

**EXCLUSIVE DISTRIBUTOR**  
Exclusively distributed by:  
Karaway Product Inc.  
Compton, CA 90220  
www.karaway.com  
Made in China

3 Cut along dotted line

**Pure-Aid™**

**MAXIMUM STRENGTH**

**LIDOCAINE**

*Plus Menthol*

**Targeted Immediate Pain Relief**

- ▶ Desensitizes Aggravated Nerve Pain
- ▶ Dual Action with Lidocaine and Menthol
- ▶ Fast Acting and Long Lasting
- ▶ First Aid for Pain

**For back, neck, leg, and muscle pain**

Pain relieving ointment on a breathable adhesive patch

**1 Patch 3-15/16" x 5-1/2" (10 cm x 14 cm)**

## PURE-AID

lidocaine, menthol patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67510-0284
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	240 mg
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	60 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>DIHYDROXYALUMINUM AMINOACETATE</b> (UNII: DO250MG0W6)	
<b>GLYCEROL FORMAL</b> (UNII: 3L7GR2604E)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	

<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TARTARIC ACID</b> (UNII: W48881119H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYACRYLIC ACID (250000 MW)</b> (UNII: 9G2MAD7J6W)	
<b>SODIUM POLYACRYLATE (250000 MW)</b> (UNII: 05115JN12J)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0284-1	1 in 1 POUCH; Type 0: Not a Combination Product	03/02/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/02/2018	

**Labeler** - Kareway Product, Inc. (121840057)

Revised: 3/2018

Kareway Product, Inc.