

SOUNDBODY- 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.

Soundbody 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	
Active ingredient	Purpose
Lidocaine 4%	Topical Anesthetic
Menthol 1%	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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	* This product is not manufactured or distributed by Chattem, Inc, owner of the registered trademark IcyHot®. Manufactured for Big Lots Stores, Inc. by Kareway Product, Inc., 2550 S. Dominguez Hills Dr. Compton, CA 90220 V#1005684 MADE IN CHINA ITEM# 0636
Comments or Questions? 1-800-883-0085	

✂ Cut along dotted line

Compare to the active ingredient in IcyHot® Lidocaine Patch*

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

For back, neck, leg & arm pain relieving ointment on a breathable adhesive pad

1 LARGE PATCH
3 15/16" X 5 1/2"
(10cm X 14cm)

SOUNDBODY

lidocaine, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0636
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: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg

Inactive Ingredients

Ingredient Name	Strength

DIHYDROXYALUMINUM AMINO ACETATE (UNII: DO250MG0W6)
GLYCERIN (UNII: PDC6A3C0OX)
METHYL PARABEN (UNII: A2I8C7H9T)
KAOLIN (UNII: 24H4NWX5CO)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
TARTARIC ACID (UNII: W4888119H)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
WATER (UNII: 059QF0K00R)
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0636-1	1 in 1 POUCH; Type 0: Not a Combination Product	05/18/2018	

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: 5/2018

Kareway Product, Inc.