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.

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

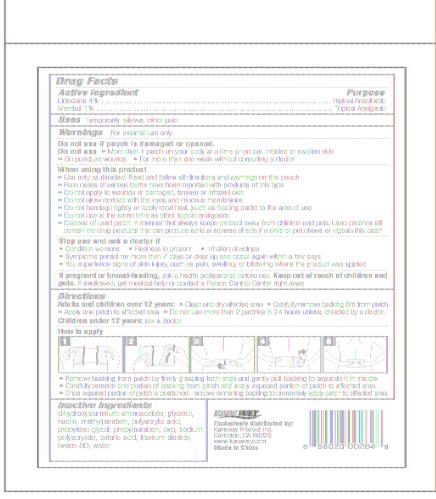
- Desensitizes Aggravated Nerves
- Dual Action with Lidocaine and Menthol
- Fast Acting and Long Lasting
- First Aid for Pain

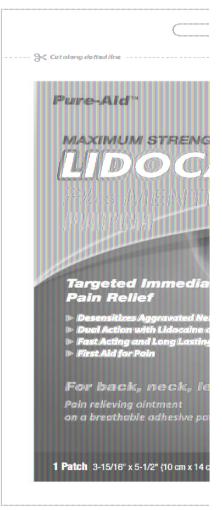
Pain Relieving Ointment on a Breathable Adhesive Pad

Contains 1 Patch

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

Label





PURE-AID

lidocaine, menthol patch

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:67510-0284

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII:98 PI200987) LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII:98 PI200987) MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A) (MENTHOL, UNSPECIFIED FORMUNII:L7T10 EIP3A) 60 mg

Inactive Ingredients			
Ingredient Name	Strength		
DIHYDRO XYALUMINUM AMINO ACETATE (UNII: DO 250 MG0 W6)			
GLYCEROL FORMAL (UNII: 3L7GR2604E)			
METHYLPARABEN (UNII: A218 C7H19 T)			
KAOLIN (UNII: 24H4NWX5CO)			

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
WATER (UNII: 059QF0KO0R)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	

F	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.