LIDOCAINE PAIN RELIEF- lidocaine pain relief patch **PAI Holdings, LLC**

Maximum Strength

Lidocaine Pain Relief Patch

4% Lidocaine ι Topical Anesthetic

Active ingredient(s)

Lidocaine 4%

Purpose

Topical anesthetic

Uses

Temporary relief of pain

Warnings

For external use only

Do not use

- more than one patch at a time
- on wounds or damaged, broken or irritated skin
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
 read and follow all directions and warnings
- do not allow contact with eyes and mucous membranes
- do not bandage tightly
 do not apply local heat such as a heating pad
- do not use other topical anesthetics at the same time

Stop use and ask a doctor if

- localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

if pregnant or breast-feeding,

ask a healthcare professional before use.

Keep out of reach of children

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 film from patch and apply to the skin
- apply one patch to affected area not more than 3 to 4 times a day
- remove patch from the skin after at most 12-hour application

Children under 12 years of age: consult a doctor

Inactive ingredients

dihydroxyaluminum aminoacetate, disodium edetate, gelatin, glycerin, kaolin, methylparaben, polyacrylic acid, polyvinyl alcohol, propylene glycol, propylparaben, sodium carboxymethylcellulose, sodium polyacrylate, D-sorbitol, tartaric acid, urea, water

Comments or Questions:

1-800-845-8210

††This product is not manufactured or distributed by Chattem, Inc., distributor of Aspercreme® Lidocaine Patch.

Distributed by



MADE IN JAPAN

C09750050222 R02/22

Principal Display Panel



lidocaine patch

LIDOCAINE PAIN RELIEF

lidocaine pain relief patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-0970
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	560 mg	

Inactive Ingredients	
Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYVINYL ALCOHOL (100000 MW) (UNII: 949E52Z6MY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)	
SORBITOL (UNII: 506T60A25R)	
TARTARIC ACID (UNII: W4888I119H)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0970- 05	12 in 1 CASE	04/03/2023	
1		5 in 1 CARTON		
1	NDC:0121-0970- 01	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	04/03/2023	

Labeler - PAI Holdings, LLC (044940096)

Revised: 11/2023 PAI Holdings, LLC