CVS HEALTH LIDOCAINE PAIN-RELIEVING- lidocaine patch Natural Essentials, 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.

Drug Facts

Active ingredients

Lidocaine 4%

Purpose

Topical Anesthetic

Use

For the temporary relief of 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 carton.
- Do not use more than one patch in an 8 hour period. Maximum 3 patches per day.
- 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
- NOTE: patches may not adhere as well to all individuals, skin types, or certain parts of the body.

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 physician before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults/children 12 years and older
- 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 completely to apply patch to affected area
- once applied, press firmly and rub on all sides and center of patch to help adhesive adhere to skin
- do not remove patch and reapply, this will result in the patch not sticking
- avoid strenuous exercise while wearing patch, this will result in patch not sticking
- do not use more than one patch in an 8 hour period.

Children 12 years or younger: ask a doctor.

Other information

Store at room temperature - do not exceed 86° Fahrenheit, 30° Celsius.

Inactive ingredients

Aluminum Glycinate, Glycerin, Kaolin, Methylparaben, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, Propylparaben, Povidone, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water.

Principal Display Panel - 567 mg Carton Label

CVS Health™

Compare to the active ingredient in Salonpas® 4% Lidocaine Gel Patch*

MAXIMUM STRENGTH

Lidocaine concentration without a prescription[†]

Lidocaine Pain-Relieving Patch

LIDOCAINE 4% GEL

Numbing muscle & joint relief

For temporary relief of minor aches & pains:

- Arthritis
- Bruises
- Strains & sprains

Unscented

6 PATCHES

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

[†]Among over the counter topical analgesics.



Principal Display Panel - 567 mg Vial Label

CVS Health™

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1 PATCH

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MAXIMUM STRENGTH Lidocaine concentration without a prescription[†]

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How to apply:



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CVS HEALTH LIDOCAINE PAIN-RELIEVING

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-276
Route of Administration	TRANS DERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	567 mg

Inactive Ingredients	
Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A218C7HI9T)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

F	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66902-276- 06	6 in 1 BOX	12/18/2019		
1		1 in 1 PATCH; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/18/2019	

Labeler - Natural Essentials, Inc. (947484713)

Establishment				
Name	Address	ID/FEI	Business Operations	
Foshan Aqua Gel Biotech Co., Ltd.		529128763	MANUFACTURE(66902-276)	

Revised: 10/2022 Natural Essentials, Inc.