CVS PAIN RELIEF- 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 ingredient

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 allow contact with the eyes
- 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 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 to completely apply patch to affected area
- use 1 patch for up to 12 hours

Children 12 years or younger: ask a doctor

Other information

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

Inactive ingredients

Benzyl Alcohol, Carboxymethylcellulose Sodium, Dihydroxyaluminium Aminoacetate, Glycerin, Kaolin, Partially Neutralized Polyacrylate, Polysorbate 80, Polyvinyl Pyrrolidone 90, Propylene Glycol, Tartaric Acid, Tetrasodium Edetate, Titanium Dioxide, Urea, Water.

Principal Display Panel - Carton Label

CVS Health™

Compare to the active ingredient in Aspercreme® Lidocaine Patch*

MAXIMUM STRENGTH

NDC 66902-203-05

Pain Relief Patch

UP TO 12 HOURS

ODOR FREE

LIDOCAINE 4%

- Desensitizes aggravated nerves
- Fast acting
- Easy to apply
- No irritation or burning

Topical Anesthetic

Package Contains 5 Individually Wrapped Patches

5 PATCHES

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



Principal Display Panel - Pouch Label

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CVS PAIN RELIEF

lidocaine patch

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66902-203

Route of Administration TRANSDERMAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthLIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII: 98 PI200987)LIDO CAINE40 mg

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
DIHYDRO XYALUMINUM AMINO ACETATE (UNII: DO 250 MG0 W6)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PO VIDONE K90 (UNII: RDH86HJV5Z)	
PROPYLENE GLYCOL (UNII: 6DC9O167V3)	

TARTARIC ACID (UNII: W4888I119H)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	

	Packaging					
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:66902-203-05	5 in 1 BOX	12/0 1/20 17			
	l	1 in 1 POUCH				
	L	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	12/0 1/20 17			

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment					
Name	Address	ID/FEI	Business Operations		
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-203)		

Revised: 12/2017 NATURAL ESSENTIALS, INC.