KROGER PAIN RELIEF LIDOCAINE PATCH- lidocaine patch Kroger Company

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.

Kroger Pain Relief 4% Lidocaine Patch

Active Ingredient

Lidocaine 4%

Purpose

Topical anesthetic

Use

Temporary relieves minor pain

Warnings

For external use only

Do not Use

- 1. more than 1 patch on your body at a time
- 2. on cut, irritated or swollen skin
- 3. On puncture wounds
- 4. For more than one week without consulting a doctor
- 5. If you are allergic to any active or inactive ingredients

if pouch is damaged or opened

When using this product

- 1. Use only as directed
- 2. Read and follow all directions and warnings on this carton
- 3. Do not allow contact with the eyes
- 4. Do not use at the same time as other topical analgesics
- 5. Do not bandage tightly or apply local heat (such as heating pads) to the area of use

- 6. Do not microwave
- 7. Dispose of used patch in manner that always keeps product away from children or 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 consult a doctor

- 1. condition worsens
- 2. redness is present
- 3. irritation develops
- 4. symptoms persist for more than 7 days or clear up and occur again within a few days
- 5. you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breastfeeding

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 1-800-222-1222 right away

Directions

- 1. clean and dry affected area
- 2. carefully remove backing from patch starting at the corner
- 3. Apply sticky side of patch to affected area.
- 4. Use one patch for up to 12 hours.
- 5. Discard patch after single use

children under 12 years or age: consult a physician

Other Information

Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture

Inactive Ingredients

aluminum glycinate, carboxymethylcellulose sodium, glycerin, iodopropynyl butylcarbamate, kaolin, petrolatum, phenoxyethanol, polyacrylic acid, polysorbate 80, povidone, propylene glycol, sodium polyacrylate, tartaric acid, titanium dioxide, water, 3-(2-ethylhexyloxy)propane-1,2-diol

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lidocaine patch

Product Information					
Product Type	HUMAN OTC DRUG	Item Code	e (Source)	NDC:3	0142-583
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength		Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)			LIDOCAINE		4 g in 100 g

Inactive Ingredients		
	Ingredient Name	Strength
KAOLIN (UNII: 24H4NWX5CO)		

POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888I119H)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-583- 06	6 in 1 CARTON	04/01/2023	
1		1 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	04/01/2023		

Labeler - Kroger Company (006999528)

Establishment					
Name	Address	ID/FEI	Business Operations		
Foshan Aqua Gel Biotech LLC		529128763	manufacture(30142-583)		

Revised: 4/2023 Kroger Company