LIDOCAINE 4 PERCENT- lidocaine patch ARI BRANDS, LLC

Lidocaine Patch

Lidocaine 4% Patch

Drug Facts

Active ingredient

Lidocaine 4%

Purpose

External analgesic

Uses

Temporarily relieves pain and itching associated with:

- minor burns
- sunburn
- minor cuts
- scrapes
- insect bites
- · minor skin irritations

Warnings

For external use only.

Read all warnings and directions before use.

Do not use

- More than one patch at a time
- On wounds or damaged skin
- With a heating pad
- If you are allergic to any ingredients of this product

Allergy Alert: if you are allergic to any inactive ingredient of this product, contact a doctor before use.

When using this product

- Use only as directed.
- Avoid contact with eyes, mucous membranes, or rashes
- Do not tightly wrap or bandage the treated area

Stop use and ask a physician:

- If pregnant or breast feeding
- If localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling, and blistering
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 12 years of age and older:

Apply 1 patch to the affected area of intact skin up to 3 times a day. Do not leave patch on for more than 8 hours at a time.

- Clean and dry the affected area.
- Open pouch and remove one patch.
- Remove any protective film and apply directly to affected area of pain. Apply immediately after removal from the protective envelope.
- Wash hands with soap and water after handling the patches.
- Reseal pouch containing unused patches after each use. Do not store patch outside the sealed envelope.
- Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

Children under 12 years: Ask a physician

Other information

Store at room temperature 15°-30°C (59°-86°F)

Avoid storing product in direct sunlight and protect product from excessive moisture.

Inactive ingredients

Aqua (Deionized Water), Glycerin, Sodium Polyacrylate, Propylene Glycol, Polysorbate 80, Tartaric Acid, Dihydroxyaluminum Aminoacetate, Methylparaben, Peppermint Oil

PRINCIPAL DISPLAY PANEL

Lidocaine 4% Patch

NDC 71436-3104-1

10 Patches per Box

AriBrands, LLC



Drug Facts

Active ingredients:

Lidocaine 4% External Analgesic

Temporarily relieves pain and fiching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, or minor skin irritations.

Adults and children 12 years and over: Apply 1 patch to the affected area of intact skin up to 3 times a day. Do not leave patch on for more than 8 hours at

Instructions for Use:

- Clean and dry the affected area.
- Open pouch and remove one patch.
- Remove any protective film and apply directly to affected area of pain. Apply immediately after removal from the protective envelope.
- Wash hands with soap and water after handling the patches
- Reseal pouch containing unused patches after each use. Do not store patch outside the sealed envelope.
- Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them. Children under 12 years: Ask a physician

Warnings:

- For external use only. Read all warnings and directions before use.
- Do not use More than one patch at a time On wounds or damaged skin With a heating pad If you are allergic to any ingredients of this product
- Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center immediately
- Stop use and ask a physician:
 - · If pregnant or breast feeding
 - If localized skin reactions occur, such as tash, itching, redness, imitation, pain, swelling, and blistering

STORE IN A DRY, COOL PLACE.

- . If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within
- a few days, discontinue use of the product and consult a physician
- Allergy Alert: if you are allergic to any inactive ingredient of this product, contact a doctor before use.
- When using this product: Use only as directed Avoid contact with eyes, mucous membranes, or rashes Do not lightly wrap or bandage the treated area

Other Ingredients:

Aqua (Deionized Water), Glycerin, Sodium Polyacrylate, Propylene Glycol, Polyacrbate 80, Tartaric Acid, Dihydroxyaluminium Aminoacetate, Methylparaben. Peopermint Oil

Other Information

Store at room temperature 15°-30°C (59°-86°F)

Avoid storing product in direct sunlight and protect product from excessive moisture

Manufactured for: AriBrands, LLC,

Los Angeles, CA 90064

Qty: 10 Articulated Patches 5 (Per Reseable Pouch) x 2

LIDOCAINE 4 PERCENT

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71436-3104
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		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
TARTARIC ACID (UNII: W4888I119H)			
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PEPPERMINT OIL (UNII: AV092KU4JH)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:71436- 3104-1	10 in 1 BOX	10/01/2023			
1		1 g 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 Drug	M017	10/01/2023		

Labeler - ARI BRANDS, LLC (080658382)

Revised: 11/2023 ARI BRANDS, LLC