

**COLD AND HEAT LIDOCAINE PATCH PLUS MENTHOL- lidocaine, menthol patch
Cardinal Health, 110 dba LEADER**

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.

Leader Cold and Heat Lidocaine Patch Plus Menthol

Drug Facts

Lidocaine 4% Topical Anesthetic

Menthol 1% Topical Anesthetic

Topical Anesthetic

USES

Temporary relief of minor pain

WARNINGS

- For External use only. Use only as directed.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
- More than one patch on your body at a time
- On cut, irritated or swollen skin
- On puncture wounds
- For more than one week without consulting a doctor
- If you are allergic to any active or inactive ingredients
- If pouch is damaged or opened.

If pregnant or breast feeding

- Contact a physician prior to use.

WHEN USING:

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

- Do not microwave

- 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 consult 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.

DIRECTIONS Adults and children 12 years of age and over:

Clean and dry affected area. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard after single use. Children under 12 years of age: consult a physician.

INACTIVE INGREDIENTS

aluminum glycinat e, glycerin, kaolin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol, propylparaben, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water

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

Lidocaine + Menthol Patch

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

Maximum Strength Lidocaine
Cold & Hot Patch Plus Menthol
 Lidocaine, 4% | Menthol, 1%
 Topical Anesthetic | Topical Analgesic



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Drug Facts

Active ingredient Purposes
 Lidocaine, 4% Topical Anesthetic
 Menthol, 1% Topical Analgesic

Use: Temporarily relieves minor pain.

Warnings

For external use only.
 Do not use: More than one patch on your body at a time. On cat, irritated or swollen skin. On puncture wounds. For rashes that are itchy without consulting a doctor. If you are allergic to any active or inactive ingredients or if patch is damaged or expired.

When using this product: Use only as directed. Read and follow all directions and warnings on this carton. Do not rub, contact with the eyes and mucous membranes. Do not use at the same time as other topical anesthetics. Do not use on a baby's tummy or apply near their face. Heating pads to the area of use. Do not microwave. 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 swallowed or ingested. This patch may cause dizziness. Burns have been reported with patches of this type. Do not apply to wounds or damaged, broken or irritated skin.

Stop use and consult a doctor if a condition worsens or becomes present or increases in severity. 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 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 800-525-1222 right away.

Directions: Adults and children 12 years of age and over: Clean and dry affected area. Carefully remove backing from patch, leaving it in place. Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after 12 hours use. Children under 12 years of age: consult a physician.

Other information: Store in a cool, dry place out of direct sunlight. Protect from excessive moisture.

Inactive ingredients: aurotrium phosphate, glycerin, heparin, methylparaben, polyacrylic acid, polyacrylate, propylene glycol, propylparaben, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water.

Questions or comments? Call 1-866-328-1913



Maximum Strength Lidocaine
Cold & Hot Patch Plus Menthol
 Lidocaine, 4% | Menthol, 1%
 Topical Anesthetic | Topical Analgesic



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 Lidocaine, 4%
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 Topical Anesthetic
 Topical Analgesic

Desensitizes Aggravated Nerves and Relieves Pain
 No-Mess, Single-Use Application
 Stay-Put Flexible Patch

COMPARE TO ICY HOT® LIDOCAINE PLUS MENTHOL PATCH active ingredients*
100% Money Back Guarantee

5 PATCHES
 3.93 in. x 5.51 in. (10 cm x 14 cm)

✓
 All LEADER® Brand Products Have A
100% Money Back Guarantee
 Return to place of purchase if not satisfied.

*This product is not a manufacturer distributed by Cardinal Health, Inc., distributor of Icy Hot® Lidocaine Plus Menthol Patches.

CardinalHealth®
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 Made in China



Child Resistant Packaging
 92-77050 04/20 VCS10044

LOT _____
 EXP _____

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COLD AND HEAT LIDOCAINE PATCH PLUS MENTHOL

lidocaine, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0558
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
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL 1-(2-METHYLBUTYRATE) (UNII: 9Q5W5G6461)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0558-1	5 in 1 POUCH	07/01/2018	
1		9 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2018	

Labeler - Cardinal Health, 110 dba LEADER (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(70000-0558)

Revised: 1/2023

Cardinal Health, 110 dba LEADER