

TOPCARE PAIN RELIEF PATCH- lidocaine, menthol patch
Topco Associates LLC

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.

TopCare Pain Relief Patch Lidocaine plus Menthol

Active ingredients

Lidocaine 4%

Menthol 1%

Purposes

Topical anesthetic

Topical analgesic

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
- 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

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 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 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 health professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center 800-222-1222 right away.

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
- Dispatch patch after a single use.
- **children under 12 years of age:** consult a physician

Inactive ingredients

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

Package/Label Principal Display Panel



Drug Facts

Active Ingredients: Lidocaine 4.0% (Topical anesthetic), Menthol 1.0% (Topical analgesic)

Use: Temporarily relieves minor pain.

Warnings: For external use only. Do not use in more than one patch on your body at a time or on cut, irritated or swollen skin. Do not use on puncture wounds or for more than one week without consulting a doctor. Do not use on any other sensitive or sensitive ingredients if it pricks, itches, stings or causes irritation.

When using this product: Use only as directed. Do not use on any other sensitive or sensitive ingredients if it pricks, itches, stings or causes irritation. Do not use on any other sensitive or sensitive ingredients if it pricks, itches, stings or causes irritation. Do not use on any other sensitive or sensitive ingredients if it pricks, itches, stings or causes irritation.

Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center 800-235-1223 right away.

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 patch after single use. Children under 12 years of age: consult a physician.

Other Information: None in use, dry places outside of direct sunlight. Protect from excessive moisture.

Inactive Ingredients: aluminum glycinate, glycerin, isobutyl alcohol, polyacrylic acid, polyacrylate G1, propylene glycol, polyisobutylene, PVP, sodium polyacrylate, butylacrylate, butyl methacrylate, urethane.

DISTRIBUTED BY TOPCARE ASSOCIATES LLC
 1155 BRIDGE PLAZA, SUITE 2000
 CANTON, MISSISSIPPI 39021
 1-800-425-4138
 www.topcare.com www.topcareusa.com
 MADE IN CHINA

Scan here for more information
 or call 1-800-425-4138

0 36800 49585 2

TopCare health **MAXIMUM STRENGTH LIDOCAINE**
Pain Relief Patch
 4% Lidocaine • 1 % Menthol

NDC 76162-007-05

TopCare health **MAXIMUM STRENGTH LIDOCAINE**
Pain Relief Patch
 4% Lidocaine • 1 % Menthol

COMPARE TO ICY HOT® LIDOCAINE PATCH PLUS MENTHOL ACTIVE INGREDIENTS*

MAXIMUM STRENGTH LIDOCAINE
Pain Relief Patch
 4% Lidocaine • 1 % Menthol

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

LASTS UP TO 12 HOURS

BACK, NECK, LEG & SHOULDER

5 PATCHES
 3.53" X 5.5" (10 cm X 14 cm) EACH

TopCare health **MAXIMUM STRENGTH LIDOCAINE**
Pain Relief Patch
 4% Lidocaine • 1 % Menthol

*Icy Hot is a registered trademark of Choline, Inc. Choline, Inc. is not affiliated with TopCare or this product.

QUALITY GUARANTEED
 This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

Child-Resistant Packaging
 Model 23-912
 92-52018 01/22 VCS10046

LOT
 EXP

TOPCARE PAIN RELIEF PATCH			
lidocaine, menthol patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-007
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, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g
Inactive Ingredients			
	Ingredient Name		Strength
	DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)		
	SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)		
	POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		

GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-007-05	5 in 1 CARTON	01/01/2022	
1		1 g in 1 POUCH; 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	01/01/2022	

Labeler - Topco Associates LLC (006935977)

Establishment			
Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd		529128763	manufacture(76162-007)

Revised: 1/2022

Topco Associates LLC