

**PAIN RELIEF GEL-PATCH- lidocaine, menthol patch
R & Y Group, LLC**

TheraICE™ Lidocaine&Menthol Pain Relief Gel-Patch, 7 Patches

Active Ingredients

Lidocaine 4% w/w Purpose: Topical Anesthetic

Menthol 1% w/w Purpose: Topical Analgesic

Purpose

Topical Anesthetic (Lidocaine)

Topical Analgesic (Menthol)

Use

for temporary relief of pain

Warnings

For External Use Only

Do not use

- More than 1 patch at a time
- If you are allergic to any ingredients of this product
- On wounds or damaged skin
- In large quantities, particularly over raw surfaces or blistered areas

When using this product

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

Stop use and consult a doctor if

- Localized skin reactions occur, such as a rash, itching, redness, irritation, pain, swelling and blistering
- Conditions worsen
- Symptoms clear up and occur again within a few days
- Symptoms persist for more than 7 days

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 and Children 12 years of age and over.

- Clean and dry affected area
- Remove film from patch and apply to the skin
- Apply to affected area not more than 3 to 4 times daily
- Remove patch from the skin after 8-hour application at most

Children under 12 years of age: Consult a physician

Other Information

- Store at 68° - 77° F (20° - 25° C)
- Store in a cool dry place away from direct sunlight

Inactive Ingredients

Dihydroxyaluminium Aminoacetate, Edetate Disodium, Glycerin, Hydroxyacetophenone, Kaolin, L(+)-Tartaric Acid, Mineral Oil, Polyacrylic Acid, Polysorbate 80, Polyvinylpyrrolidone K90, Propylene Glycol, Sodium Polyacrylate, Titanium Dioxide, Water

Package label. Principal display panel

CUT HERE



TheraICE™

PAIN RELIEF GEL-PATCH

LIDOCAINE 4% + MENTHOL 1%



TOPICAL ANALGESIC

SINGLE USE
FOR TEMPORARY PAIN RELIEF

NO MESS
EASY TO APPLY AND REMOVE

LASTS UP TO 8 HOURS

1 PATCH
5.5 in. x 3.94 in.
(10 cm x 14 cm) each

5mm



TheraICE™

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LOT



Manufactured for: R&Y Group LLC
20264 NE 15 Ct., Miami, FL 33179
www.theraice.com

For issues with your product please contact us at info@theraice.com

Drug Facts (continued)

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TI-PATCH-LM-1



CHILD-RESISTANT PACKAGING

MADE IN CHINA



TheraICE™

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TheraICE Rx Lidocaine & Menthol Pain Relief Patch - 7 pack New

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LOT



MADE IN CHINA

PAIN RELIEF GEL-PATCH

lidocaine, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83016-171
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.12 g in 12 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.48 g in 12 g

Inactive Ingredients

Ingredient Name	Strength
KAOLIN (UNII: 24H4NWX5CO)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0KO0R)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83016-171-07	7 in 1 POUCH	06/15/2023	
1	NDC:83016-171-01	12 g in 1 PACKET; 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	06/15/2023	

Labeler - R & Y Group, LLC (968585765)

Registrant - Shanghai Chuangshi Medical Technology (Group) Co., Ltd. (546872672)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Chuangshi Medical Technology (Group) Co., Ltd.		546872672	manufacture(83016-171)

Revised: 10/2024

R & Y Group, LLC