

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

TheralCE™ 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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Drug Facts

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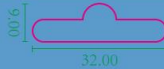
Dihydroxyaluminum Aminoacetate, Edetate Disodium, Glycerin, Hydroxyacetophenone, Kaolin, L (+)- Tartaric Acid, Mineral Oil, Polyacrylic Acid, Polysorbate 80, Polyvinylpyrrolidone K90, Propylene Glycol, Sodium Polyacrylate, Titanium Dioxide, Water

TI-PATCH-LM-1



CHILD-RESISTANT PACKAGING

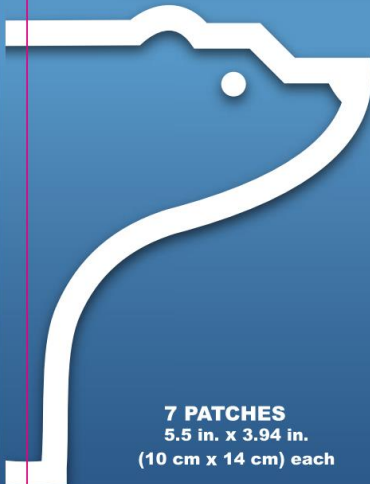
MADE IN CHINA



TheraICE™

PAIN RELIEF GEL-PATCH

LIDOCAINE 4% + MENTHOL 1%



TOPICAL ANALGESIC

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5mm

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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 not final	part348	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: 6/2023

R & Y Group, LLC