## PAIN RELIEF GEL-PATCH- lidocaine and menthol patch Shanghai Chuangshi Medical Technology (Group) Co., Ltd.

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## Zeey, LIDOCAINE&MENTHOL PAIN RELIEF GEL-PATCH, N 5, N 10, N 15

#### **Active Ingredient**

Lidocaine 4% w/w ..... Purpose: Topical anesthetic Menthol 1% w/w ..... Purpose: Topical analgesic

## Purposes

Topical anesthetic (Lidocaine) Topical analgesic (Menthol)

## Uses

For temporary relief of pain

## Warnings

For external use only

#### When using this product:

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

## Do not use:

- More than 1 patch at a time
- On wounds or damaged skin
- For more than one week without consulting a doctor
- If you are allergic to any ingredients of this product

## Stop use and ask a doctor if:

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

## If pregnant or breast-feeding,

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

# Directions

# Adult and Children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

# Children under 12 years of age: Consult a doctor

# **Inactive Ingredients**

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

# Questions or Comments

1 646-223-0128 · Lu.FDAmanage@gmail.com

# Other information

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

# Package label. Principal display panel









PAIN RELIEF GEL-PA	тсн				
idocaine and menthol patch					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:73557-172	
Route of Administration	TOPICAL				
	-				
Active Ingredient/Active	Moiety				
Ingredi	ient Name		Basis of Streng	th	Strength
MENTHOL (UNII: L7T10EIP3A) (MEN	NTHOL - UNII:L7T10EIP3A)		MENTHOL	0	.01g in 1g
LIDOCAINE (UNII: 98PI200987) (LIE	DOCAINE - UNII:98PI200987)		LIDOCAINE	0	.04 g in 1 g
Institus Ingradianta					
Inactive Ingredients					
	Ingredient Name				Strength
KAOLIN (UNII: 24H4NWX5CO)					
TARTARIC ACID (UNII: W48881119	H)				
WATER (UNII: 059QF0K00R)					

DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)				
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JNI2J)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
MINERAL OIL (UNII: T5L8T28FGP)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				
GLYCERIN (UNII: PDC6A3C0OX)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
POVIDONE K90 (UNII: RDH86HJV5Z)				
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)				

#### **Product Characteristics** Color white Score Size Shape Flavor **Imprint Code** Contains

## Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73557-172- 05	5 in 1 BOX	12/30/2022	
1	NDC:73557-172- 01	12 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:73557-172- 10	10 in 1 BOX	01/09/2024	
2	NDC:73557-172- 01	12 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:73557-172- 15	15 in 1 BOX	01/09/2024	
3	NDC:73557-172- 01	12 g in 1 PATCH; Type 0: Not a Combination Product		
Marketing Information				
	Markoting	Application Number or Menograph	Markoting Start	Markoting End

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M017	12/30/2022	

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

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

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>

Shanghai Chuangshi Medical Technology (Group) Co., manufacture(73557-172), label(73557-

Revised: 4/2024

Shanghai Chuangshi Medical Technology (Group) Co., Ltd.