# LIDOSPOT PATCH- lidocaine and menthol patch Fabrication Enterprises Inc

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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

Temporarily relieves minor pain.

### Warnings

# For external use only

# When using this product:

- Use only as directed
- Read and follow all directions and warnings on this carton
- Do not alow 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 stil containthe drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

#### 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.

### 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 experiencesigns 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.

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 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.

Children under 12 years of age: consult a physician.

# **Inactive Ingredients**

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

# Questions or Comments

1-800-431-2830

#### Other information

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

# Package label. Principal display panel





# **LIDOSPOT PATCH**

lidocaine and menthol patch

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51452-172

**Route of Administration** TOPICAL

# **Active Ingredient/Active Moiety**

I	Ingredient Name	<b>Basis of Strength</b>	Strength
I	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.01 g in 1 g
I	LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 g in 1 g

Inactiva	Ingredients
IIIactive	mureulents

mactive ingredients	
Ingredient Name	Strength
KAOLIN (UNII: 24H4NWX5CO)	
TARTARIC ACID (UNII: W48881119H)	

WATER (UNII: 059QF0KOOR)

DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)

SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)

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)

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

ı	Packaging				
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:51452-172- 05	5 in 1 BOX	07/21/2025		
:	NDC:51452-172- 01	12 g in 1 PATCH; 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	07/21/2025		

# Labeler - Fabrication Enterprises Inc (070577218)

# Registrant - Fabrication Enterprises Inc (070577218)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Shanghai Chuangshi Medical Technology (Group) Co., Ltd.		546872672	manufacture(51452-172)

Revised: 7/2025 Fabrication Enterprises Inc