POINT RELIEF LIDOSPOT- lidocaine, menthol patch
Fabrication Enterprises

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.

FEI LIDOCAINE&MENTHOL PAIN RELIEF GEL-PATCH, 5 Patches

Active ingredient

Lidocaine 4.0% w/w ..... Purpose: Topical anesthetic

Menthol 1.0% 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 allow contact with the eyes
- Do not use at the same time as other 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.

Do not use

- More than one 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 consult a doctor if

- Condition worsen
- 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 applied.

If pregnant or breastfeeding,

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 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 stickly 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

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

Other information

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

Package label. Principal display panel

5mm

CUT OPEN POUCH AND REMOVE PAD

5mm

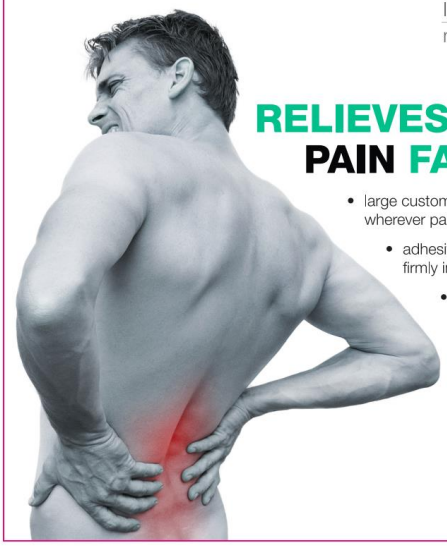
NDC xxxxx-xxx-xx

point relief®

lidospot® patch

topical anesthetic

lidocaine	4%
menthol	1%



RELIEVES PAIN FAST

- large customizable size fits wherever pain relief is needed
- adhesive keeps patch firmly in place
- provides pain relief up to 12 hours

1 patch

4 x 5.5 inch
(10cm x 14cm)

170mm

140mm

CUT OPEN POUCH AND REMOVE PAD

point relief® lidospot® patch
topical anesthetic

Manufactured For:
Fabrication Enterprises Inc.
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Elmsford, NY 10523 (USA)
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FabEnt.com

FEI

EC REP

CE AJW Technology Consulting GmbH
Breite Strasse 3
40213 Düsseldorf (Germany)

REF 13-5310-1
LOT
EXP

CN Made in China

Drug Facts

Active ingredient ..... ***Purposes***
Lidocaine 4.0% ..... Topical Anesthetic
Menthol 1.0% ..... Topical Analgesic

Uses Temporarily relieves minor pain.

Warnings
For external use only

Do not use ■ More than one 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 consult 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 breastfeeding, 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 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.
Children under 12 years of age: consult a physician.

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

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

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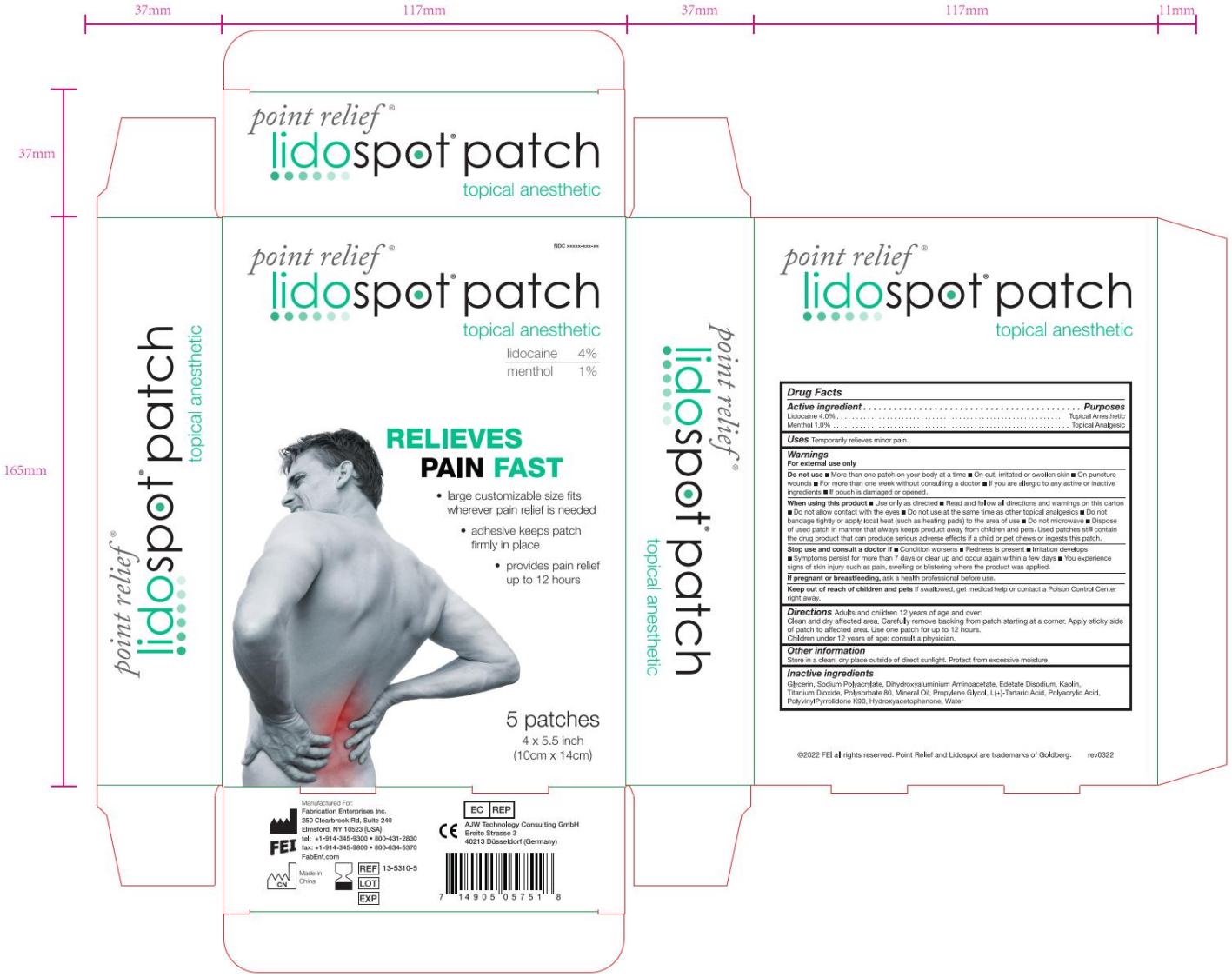
140mm



POINT RELIEF LIDOSPOT

lidocaine, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51452-173
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 3 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.12 g in 3 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: 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	brown	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-173-05	5 in 1 POUCH	04/05/2022	
1	NDC:51452-173-01	3 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 not final	part348	04/05/2022	

Labeler - Fabrication Enterprises (070577218)

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(51452-173)

Revised: 4/2022 Fabrication Enterprises