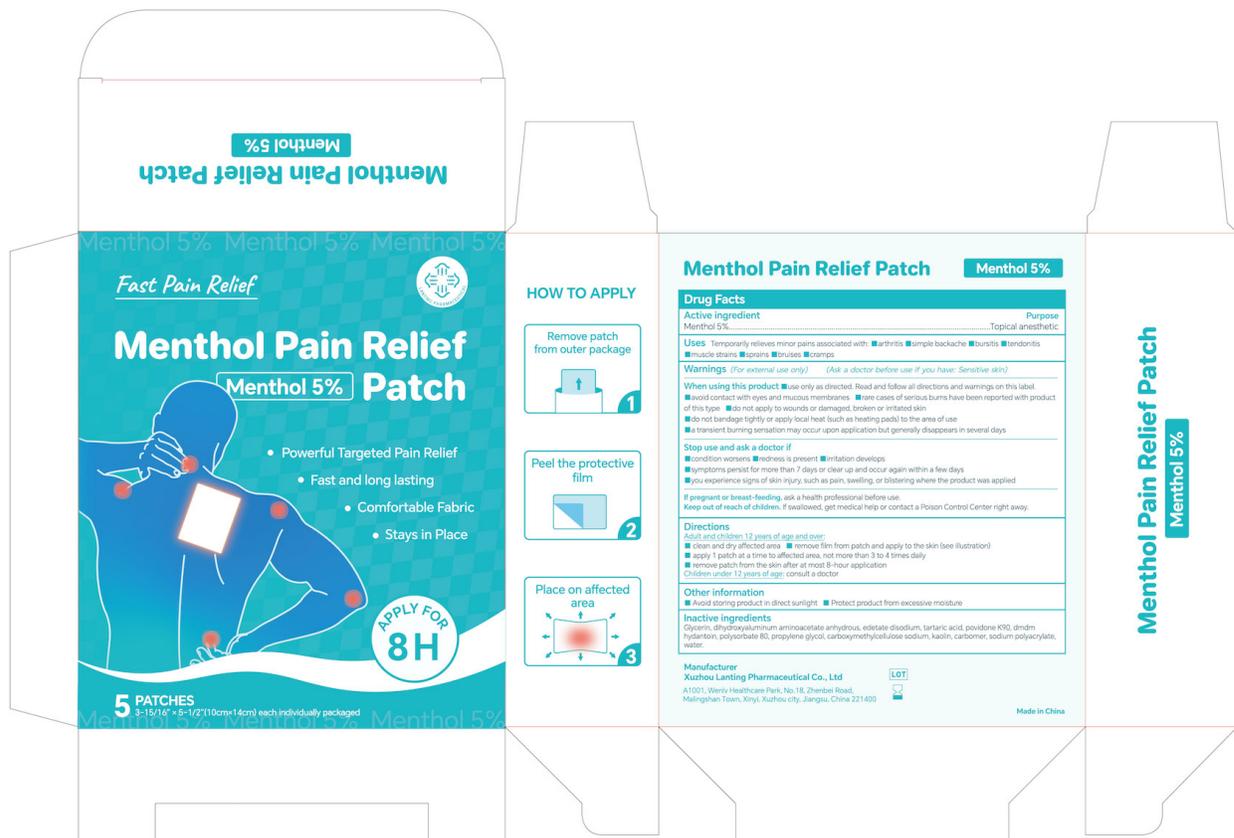


5% MENTHOL PAIN RELIEF PATCH- pain relief patch patch Xuzhou Lanting Pharmaceutical Co., Ltd

5% Menthol Pain Relief Patch, Package NDC Code 85323-004-00

5% Menthol Pain Relief Patch, Package NDC Code 85323-004-00



Active Ingredient

Active Ingredient: 5% Menthol

Purpose

Topical anesthetic

Warnings

Warnings (For external use only)

- Do not use
- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad

- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

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 experience signs 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.

Inactive Ingredients

Glycerin, dihydroxyaluminum aminoacetate anhydrous, edetate disodium, tartaric acid, povidone K90, dmdm hydantoin, polysorbate 80, propylene glycol, carboxymethylcellulose sodium, kaolin, carbomer, sodium polyacrylate, water.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Other information

- Avoid storing product in direct sunlight
- Protect product from excessive moisture

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

Uses

Temporarily relieves minor pains associated with:

arthritis

simple backache

bursitis

tendonitis

muscle strains

sprains

bruises

cramps

Directions

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5% MENTHOL PAIN RELIEF PATCH

pain relief patch patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85323-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII: BZ1R15MTK7)	LEVOMENTHOL	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
KAOLIN (UNII: 24H4NWX5CO)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
CARBOMER (UNII: 0A5MM307FC)	

GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
TARTARIC ACID (UNII: W4888I119H)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85323-004-00	5 in 1 BOX	03/01/2025	
1		1 in 1 POUCH		
1		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	505G(a)(3)	03/01/2025	

Labeler - Xuzhou Lanting Pharmaceutical Co., Ltd (457641059)

Registrant - Xuzhou Lanting Pharmaceutical Co., Ltd (457641059)

Establishment

Name	Address	ID/FEI	Business Operations
Xuzhou Lanting Pharmaceutical Co., Ltd		457641059	manufacture(85323-004)

Revised: 3/2025

Xuzhou Lanting Pharmaceutical Co., Ltd