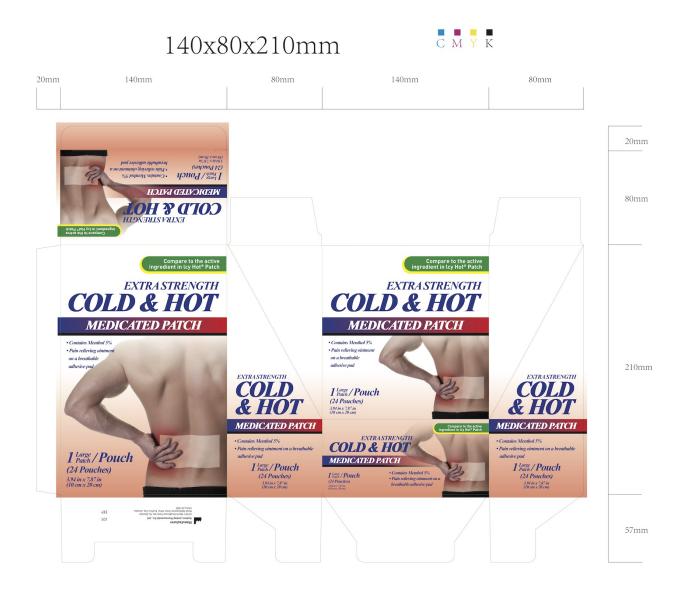
5% MENTHOL PAIN RELIEF PATCH- pain relief patch patch Xuzhou Lanting Pharmaceutical Co., Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

85323-007, 5% Menthol Pain Relief Patch

5% Menthol Pain Relief Patch, Package NDC Code 85323-007-01

5% Menthol Pain Relief Patch, Package NDC Code 85323-007-01





Active Ingredient

Active Ingredient: Menthol 5%

Purpose

Purpose: Topical anesthetic

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
- do not bandage tightly or use with a heating pad

- avoid contact with the eyes and mucous membranes
- do not apply to wounds or damaged skin.

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few day
- redness is present
- skin irritation develops

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 (1-800-222-1222) immediately.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminum Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, Povidone K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Other information

Other Information

• store at roo temperature 68 to 77°F (20 to 25°C)

Directions

Directions

Adult and children 12 years of age and older:

- peel off protective backing and apply sticky side to affected area
- carefully remove backing from patch
- should be used to 8 hours
- ashould be used no more than 3 times a day
- Children under 12 years of age: consult a doctor

Uses

Uses

Temporarily relieve minor aches and pains of muscles and joints due to

- simple backache
- arthritis
- muscle strains
- bursitis
- tendonitis
- muscle sprains
- bruises

cramps

Temporarily relieves minor pains associated with:

- arthritis
- simple backache
- muscle strains
- bursitis
- tendonitis
- sprains
- bruises
- cramps

Adult and Children 12 years of age and older:

- peel off protective backing and apply sticky side to affected area
- carefully remove backing from patch
- should be used to 8 hours
- ashould be used no more than 3 times a day
- Children under 12 years of age: consult a doctor

5% MENTHOL PAIN RELIEF PATCH pain relief patch patch **Product Information Product Type** HUMAN OTC DRUG **Route of Administration** TOPICAL

Item Code (Source)

NDC:85323-007

| Active Ingredient/Active Moiety | | | | |
|--|--------------------------|--------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 g in 100 g | | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| POLYSORBATE 80 (UNII: 60ZP39ZG8H) | |
| KAOLIN (UNII: 24H4NWX5CO) | |
| SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J) | |
| CARBOMER 934 (UNII: Z135WT9208) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K) | |
| POVIDONE K90 (UNII: RDH86HJV5Z) | |
| TARTARIC ACID (UNII: W4888I119H) | |
| ALCOHOL 95% (UNII: 7528N5H79B) | |
| | |

| Product Characteristics | | |
|-------------------------|--------------|--|
| Color | Score | |
| Shape | Size | |
| Flavor | Imprint Code | |
| Contains | | |
| | | |
| | | |
| Packaging | | |

| | # | ltem Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|----------------------|--|-------------------------|-----------------------|
| | 1 | NDC:85323-007- 01 | 24 in 1 BOX | 06/10/2025 | |
| l | 1 | | 1 in 1 POUCH | | |
| | 1 | | 19 g in 1 PATCH; Type 0: Not a Combination Product | | |

140x80x210mm





| Marketing Information | | | | |
|--------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| unapproved drug other | | 06/10/2025 | | |
| | | | | |

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(85323-007) |

Revised: 6/2025

Xuzhou Lanting Pharmaceutical Co., Ltd