

THERMAPATCH (TM) LIDOCAINE PAIN RELIEF PATCH- lidocaine pain relief patch patch

Henan Enokon Medical Instrument Co., Ltd.

83559-006

Active Ingredient

Lidocaine 4%

Purpose

Topical anesthetic

Use

For temporary relief of pain

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 have ever had an allergic reaction to this product or any of its ingredients

When Using

Use only as directed

Avoid contact with the eyes, mucous membranes or rashes

Do not bandage tightly

Stop Use

Localized skin reactions occur, such as rash, itching, redness, irritation, pain swelling, and blistering

Conditions worsen

Symptoms persist for more than 7 days

Symptoms clear up and occur again within a few days

Ask Doctor

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

Adults and children 12 years of age and over:

Clean and dry affected area

Remove film from patch and apply to the skin

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 hours of application

Children under 12 years of age: consult a doctor

Other information

Avoid storing product in direct sunlight

Protect product from excessive moisture

Store at 20-25°C (68-77°F)

Inactive ingredients

Aluminum Glycinate, Edetate Disodium, Ethylhexylglycerin, Glycerin, Kaolin, Phenoxyethanol, Polyvinylpyrrolidone, Propylene Glycol, Sodium Carboxymethylcellulose, Sodium Polyacrylate, Tartaric Acid, Water

PRINCIPAL DISPLAY PANEL

ThermaPatch™
PAIN RELIEF

Lidocaine Pain Relief Patch

Maximum Strength

- 4% Lidocaine (Topical Anesthetic)
- Desensitizes Aggrevated Nerves in Back
- Neck, Shoulders, Knees, and Elbows
- For Temporary Relief of Pain
- Fast-Acting + Numbing Relief



1
PATCH

3.9 IN x 5.5 IN (10 CM x 14 CM) EACH



Pain Relief Patch

Drug Facts

| Active ingredient | Purpose |
|-------------------|--------------------|
| Lidocaine 4% | Topical anesthetic |

Uses For temporary relief of pain

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 have ever had an allergic reaction to this product or any of its ingredients

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

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

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

Adults 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 hours of application

Children under 12 years of age: consult a doctor

Other information

- avoid storing product in direct sunlight
- protect product from excessive moisture
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Inactive ingredients

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Distributed by:

ThermaPatch™
PAIN RELIEF

Made in China



Pain Patches, LLC
515 Granby Road
Chicopee, MA 01013
USA

THERMAPATCH.CO



THERMAPATCH (TM) LIDOCAINE PAIN RELIEF PATCH

lidocaine pain relief patch patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83559-006 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 4 g in 100 |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALUMINUM GLYCINATE (UNII: 1K713C615K) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| TARTARIC ACID (UNII: W4888I119H) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

| |
|--|
| KAOLIN (UNII: 24H4NWX5CO) |
| WATER (UNII: 059QF0KO0R) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| SODIUM ACRYLATE (UNII: 7C98FKB43H) |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |
| POVIDONE (UNII: FZ989GH94E) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:83559-006-01 | 6 in 1 BOX | 11/09/2024 | |
| 1 | | 1 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 | 11/09/2024 | |

Labeler - Henan Enokon Medical Instrument Co., Ltd. (701730676)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| Henan Enokon Medical Instrument Co., Ltd. | | 701730676 | manufacture(83559-006) |

Revised: 11/2024

Henan Enokon Medical Instrument Co., Ltd.