

1ST MEDXPATCH WITH LIDOCAINE 4%- lidocaine, capsaicin, menthol, methyl salicylate patch
1ST MEDX LLC

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.

1ST MEDX (as PLD) -PATCH WITH LIDOCAINE 4% (72137-555)

ACTIVE INGREDIENTS:

CAPSAICIN 0.025%

LIDOCAINE 4%

MENTHOL 5%

METHYL SALICYLATE 20%

PURPOSE

TOPICAL ANALGESIC

USES:

FOR THE TEMPORARY RELIEF OF MINOR ACHES AND PAINS OF MUSCLES AND JOINTS ASSOCIATED WITH ARTHRITIS, SIMPLE BACKACHE, STRAINS, SPRAINS, MUSCLE SORENESS AND STIFFNESS.

WARNINGS:

FOR EXTERNAL USE ONLY.

- USE ONLY AS DIRECTED.
- AVOID CONTACT WITH EYES AND MUCOUS MEMBRANES.
- DO NOT USE ON WOUNDS, CUTS, DAMAGED OR INFECTED SKIN AS WELL AS IN THE EYES, MOUTH, GENITALS, OR ANY OTHER MUCOUS MEMBRANES.
- DO NOT COVER WITH BANDAGES.

KEEP OUT OF REACH OF CHILDREN.

IF SWALLOWED, CALL POISON CONTROL

IF CONTACT DOES OCCUR WITH EYES, RINSE WITH COLD WATER AND CALL A DOCTOR.

CHILDREN UNDER 12 YEARS OLD, CONSULT A DOCTOR BEFORE USE.

- IF YOU ARE ALLERGIC TO ANY INGREDIENTS IN THIS PRODUCT CONSULT A DOCTOR BEFORE USE.
- CONSULT YOUR PHYSICIAN: IF PREGNANT OR IF PAIN PERSISTS OR WORSENS.

DIRECTIONS:

FOR ADULTS AND CHILDREN 12 YEARS AND OVER. APPLY PATCH TO AFFECTED AREA 1 TO 2 TIMES DAILY OR AS DIRECTED BY PHYSICIAN. CLEAN AND DRY THE AFFECTED AREA. WASH HANDS WITH SOAP AND WATER AFTER APPLYING PATCH. RESEAL POUCH CONTAINING UNUSED PATCHES AFTER USE.

OTHER INFORMATION:

STORE BELOW 90°F/32°C

INACTIVE INGREDIENTS:

GLYCERIN 25%, POLYACRYLIC ACID 5%, PROPYLENE GLYCOL 2%, METHYL SALICYLATE, GLYCERIN, SODIUM POLYACRYLATE, DIHYDROXYALUMINUM AMINOACETATE, ISOPROPYL MYRISTATE, TARTARIC ACID, PROPYLENE GLYCOL, SORBITOL, EDTA2-NA, PROPYL P-HYDROXYBENZOATE, TWEEN 80, TITANIUM DIOXIDE, EXTRA MEDICAL PURIFIED WATER.

QUESTIONS?

888-319-6339



1st

Medx-Patch

With Lidocaine 4%

10 PATCHES

Patch size 10x14 cm

NDC: 72137-555-15

1st Medx-Patch

With Lidocaine 4%

Drug Facts

Active Ingredients

| | |
|-----------------------------|--------------------|
| Capsaicin 0.025% | Topical Analgesic |
| Lidocaine 4% | Topical Anesthetic |
| Menthol 5% | Topical Analgesic |
| Methyl Salicylate 20% | Topical Analgesic |

Purpose

Uses: For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, sprains, muscle soreness and stiffness.

Warnings:

For external use only.

- Use only as directed.
- Avoid contact with eyes and mucous membranes.
- Do not use with heating devices or pads.
- Do not use on wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.
- Do not cover with bandages.

Keep out of reach of children.

If swallowed, call poison control.
If contact does occur with eyes, rinse with cold water and call a doctor.

Children under 12 years old, consult a doctor before use.

- If you are allergic to any ingredients in this product consult a doctor before use.
- Consult your physician: if pregnant or if pain persists or worsens.

Directions: For adults and children 12 years and over. Apply patch to affected area 1 to 2 times daily or as directed by physician. Clean and dry the affected area. Open pouch and remove protective film and apply patch to affected area. Wash hands with soap and water after applying patch. Reseal pouch containing unused patches after use.

Other Information: Store below 90°F/32°C

Inactive Ingredients: Glycerin 25%, Polyacrylic Acid 5%, Propylene Glycol 2%, Methyl Salicylate, Glycerin, Sodium Polyacrylate, Dihydroxyaluminum Aminoacetate, Isopropyl Myristate, Tartaric Acid, Propylene Glycol, Sorbitol, EDTA2-NA, Propyl P-Hydroxybenzoate, Tween 80, Titanium Dioxide, Extra Medical Purified Water.

Questions? 888-319-6339

Manufactured for 1st-MedX

Laurelton, NY 11413
888-319-6339
info@1st-Medx.com
Made in China

1ST MedX-Patch

A combination of ingredients with analgesics and anesthetic properties are used in a unique way to maximize its pain relieving effects and to aid in addition to other therapies. This offers long lasting relief for a variety of pain conditions. 1st MedX Patch is manufactured in accordance with FDA regulations by an FDA approved manufacturer.

Active Ingredients:

Menthol 5%
Lidocaine 4%
Methyl Salicylate 20%
Capsaicin 0.0375%

Uses: This formulation can be used to assist patients in the treatment of mild to moderate acute or chronic aches or pain. Muscle or joint pain can be due to musculoligamentous strains, simple backache, tendonitis, osteoarthritis, rheumatoid arthritis, peripheral neuropathies such as diabetic neuropathy or post herpetic neuralgia, and other complex regional pains. If consulted by your physician, it may be used for other conditions as well.

Directions:

Apply patch to affected area 1 to 2 times daily or as directed by physician

Instructions for Use:

1. Clean and dry the affected area
2. Open pouch and remove one patch
3. Remove any protective film and apply directly to affected area of pain
4. Wash hands with soap and water after applying patch

5. Reseal pouch containing unused patches after each use
6. Pain relief varies from patient to patient; may need to use a few times to see benefit.

Mechanism of Action:

Menthol has some local anesthetic and counterirritant qualities and also acts as a weak kappa opioid receptor agonist making it an analgesic as well. Its ability to chemically trigger the cold-sensitive TRPM8 receptors in the skin is responsible for its cooling sensation when applied to the skin. Lastly, it enhances the efficacy of other topical applications by increasing penetration via vasodilatation.

Lidocaine is a common local anesthetic that relieves itching, burning, and pain. Topically, it blocks both initiation and conduction of nerve impulses by decreasing ionic flux through the neuronal membrane. Since it penetrates the skin, it creates an anesthetic effect by not just preventing pain signals from propagating to the brain but by stopping them before they begin.

Methyl Salicylate also known as wintergreen oil, is a natural product from many plant species. It is topically used to cause dilation of the capillaries thereby increasing blood flow to the area.

Capsaicin is an active component from chili peppers that produces a burning sensation on the skin. The true mechanism is not fully understood, but it is believed to be a neuropeptide-active agent that decreases and depletes the synthesis, storage, transport, and releases of substance P. Substance P is thought to be the principal chemical mediator of pain impulses from the periphery to the central nervous system. It is also hypothesized that substance P is released into the joint tissues where it activates an inflammatory response. When capsaicin

depletes substance P in the nerve endings, the local pain impulses can no longer be transmitted to the brain.

Warnings:

- **Only for external use only.** Use only as directed or by a health professional.
- **Do not use:** on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucus membranes.
- Do not cover with bandage.
- **Keep away from children.** Consult physician for children under 12 years.
- **Consult your physician:** if pregnant or if pain persists or worsens
- **Consult your physician:** if pain persist or worsens or if using any other topical pain products.
- Store in a dry, cool place

In Case of Ingestion or Overdose, get medical help or contact a Poison Control Center

Inactive Ingredients: Glycerin 25% polyacrylic acid 5% propylene glycol 2%, methyl salicylate, glycerin, sodium polyacrylate, dihydroxyaluminum aminoacetate, isopropyl myristate, tartaric acid, propylene glycol, Sorbitol, EDTA2-NA, propyl p-hydroxybenzoate, Tween 80, titanium dioxide, Extra Medical purified water

1ST MEDXPATCH WITH LIDOCAINE 4%

lidocaine, capsaicin, menthol, methyl salicylate patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72137-555 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | 0.025 g |
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 4 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 g |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 20 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J) | |
| DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| TARTARIC ACID (UNII: W4888I119H) | |
| SORBITOL (UNII: 506T60A25R) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72137-555-15 | 10 in 1 POUCH | 03/18/2018 | |
| 1 | NDC:72137-555-01 | 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 not final | part348 | 03/15/2018 | |

Labeler - 1ST MEDX LLC (081071002)