THERA CARE PAIN THERAPY- lidocaine patch Veridian Healthcare

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.

PAIN RELIEF PATCHES

Active Ingredients

Lidocaine 4% Topical Anesthetic

Purpose

Temporarily relieves minor pain.

Dosage and Administration

Directions Adults and children over 12 years:

- clean and dry affected area
- carefully remove backing from patch starting at corner
- apply sticky side of patch to affected area
- use one patch for up to 8 hours. Children under 12 years of age: consult a physician.

Warnings

For external use only.

Idications and Usage

Uses: Temporaily relieves minor pains.

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

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.

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.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away.

Other Safety Information

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

Inactive Ingredients

Aluminum Glycinate, Glycerin, Kaolin, Methylparaben, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, Propylparaben, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

Questions

TOLL-FREE

Customer Care Help Line 866-326-1313 Mon–Fri 8:30 am–4:30 pm CST

Manufactured For Veridian Healthcare, LLC Gurnee, IL 60031

Made in China



| THERA CARE PAIN T | HERAPY | | | | | |
|------------------------------------|----------------------|-----------------------|--|-------|---------------|--|
| Product Information | | | | | | |
| Product T ype | HUMAN OTC DRUG | Item Code (Source) ND | | NDC:7 | IDC:71101-911 | |
| Route of Administration | TOPICAL | | | | | |
| Active Ingredient/Active Mo | biety | | | | | |
| Ingredient Name Basis of Str | | | | | Strength | |
| LIDO CAINE (UNII: 98PI200987) (LII | | LIDOCAINE | | | | |
| | | | | | | |
| Inactive Ingredients | | | | | | |
| Ingredient Name | | | | | Strength | |
| Aluminum (UNII: CPD4NFA903) | | | | | | |
| Glycerin (UNII: PDC6A3C0OX) | | | | | | |
| Kaolin (UNII: 24H4NWX5CO) | | | | | | |
| Methylparaben (UNII: A2I8C7HI9T) | | | | | | |
| POLYACRYLIC ACID (300000 MW |) (UNII: A8371R0U5J) | | | | | |
| POLYSORBATE 80 (UNII: 6OZP39Z | G8H) | | | | | |
| Propylene Glycol (UNII: 6DC9Q167) | √3) | | | | | |
| Propylparaben (UNII: Z8IX2SC1OH) | | | | | | |

| COPOVIDONE K25-3 | B1 (UNII: D | 9C330MD8B) | | | | | |
|---|---|---|-------|----------------------|---------------|----------|--|
| SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JNI2J) | | | | | | | |
| TARTARIC ACID (UNII: W48881119H) | | | | | | | |
| TITANIUM DIO XIDE | (UNII: 15Fl | IX9V2JP) | | | | | |
| WATER (UNII: 059QF | 0KO0R) | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Product Charact | eristics | | | | | | |
| Color | | | Score | | | | |
| Shape | | RECTANGLE | Size | | | | |
| Flavor | | | Imp | Imprint Code | | | |
| Contains | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | | Package Description |] | Marketing Start Date | Marketing E | nd Date | |
| 1 NDC:71101-911-05 | 5 in 1 CA | RTON | 0 | 5/0 1/20 18 | | | |
| 1 | 9 g in 1 P | 9 g in 1 PATCH; Type 0: Not a Combination Product | | | | | |
| 2 NDC:71101-911-15 | 15 in 1 CARTON | | 0 | 5/0 1/20 18 | | | |
| 2 | 9 g in 1 PATCH; Type 0: Not a Combination Product | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Marketing Inf | format | ion | | | | | |
| • | Marketing Category Application Number or Monograph Citation | | ion | Marketing Start Date | Marketing E | and Date | |
| OTC monograph not fi | | | 1011 | 05/01/2018 | widt ke ung r | | |
| | mai parte | 0+0 | | 03/04/2010 | | | |
| | | | | | | | |

Labeler - Veridian Healthcare (830437997)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------------|---------|-----------|----------------------------|
| Foshan Aqua Gel Biotech Co.,Ltd. | | 529128763 | manufacture (7110 1-9 11) |

Revised: 5/2018

Veridian Healthcare