

THERA CARE 24HRS LIDOCAINE PATCH- lidocaine 4% 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.

Thera Care 24 Hour Lidocaine Patch

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 24 hours. Discard patch after single use. **Children under 12 years of age:** consult a physician.

Warnings

For external use only.

Indications and Usage

Uses: Temporarily 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 800-222-1222

Other Safety Information

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

Inactive Ingredients

Styrene Isoprene Styrene block Copolymer, Alicyclic Saturated Hydrocarbon Resin, White Mineral Oil

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

NEW

THERA CARE™

PAIN THERAPY
by Vertigan Healthcare

NDC 71101-916-06

Maximum Strength
24-Hour
4% Lidocaine Patch

BACK, NECK, LEG & SHOULDER

**Desensitizes Aggravated Nerves
and Relieves Pain**

- Consistent Drug Delivery
- Odor-Free, Super-Thin & Flexible
- No-Mess, Single-Use Application
- Made in the USA



6 PATCHES
2.91 IN. X 2.17 IN. (7.4 cm x 5.5 cm)

THERA CARE™
 PAIN THERAPY
 by THERA Healsom

Drug Facts

Active ingredient **Purpose**
 Lidocaine 4% Topical anesthetic

Use To temporarily relieve minor pain.

Warnings

For external use only

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.

When using this product ■ Use only as directed ■ Read and follow all directions and warnings on this
 product ■ 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 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 breastfeeding, ask a health professional before use.

Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control
 Center right away. 500-222-1222

Directions

Adults and children 12 years of age and over: Clean and dry affected area. Carefully remove backing
 from patch. Apply sticky side of patch to affected area. Use one patch for up to 24 hours. Discard patch
 after single use. Children under 12 years of age: consult a physician.

Other information

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

Inactive ingredients

alicyclic hydrocarbon resin, methyl oil, polyester film, silicone-coated polyester film, styrene isoprene
 styrene block copolymer

Customer Care Help Line 866-326-1313, M-F 8:30am – 4:30pm CST

lidocaine 4% patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:7110 1-9 16 |
| 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 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (STYRENE/ISOPRENE 15/85) (UNII: 1SSZ6HXE7P) | |
| HYDROGENATED C6-20 POLYOLEFIN (100 CST) (UNII: 39EYQ1W9RB) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |

Product Characteristics

| | | | |
|-----------------|-----------|---------------------|--|
| Color | | Score | |
| Shape | RECTANGLE | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|--------------------|---|----------------------|--------------------|
| 1 | NDC:7110 1-9 16-06 | 6 in 1 CARTON | 05/01/2018 | |
| 1 | | 9 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 not final | part348 | 05/01/2018 | |

Labeler - Veridian Healthcare (830437997)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|----------------|---------------|----------------------------|
| Sparsha Pharma USA, Inc. | | 079365856 | manufacture(7110 1-9 16) |