

## **THERACARE PAIN RELIEVING PATCH WITH LIDOCAINE- 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.*

-----

## **TheraCare Pain Relieving Patch with Lidocaine**

### **Active Ingredients**

Lidocaine 4%

### **Purpose**

Topical anesthetic

### **Use**

Temporary relieves minor pain

### **Warnings**

#### **For external use only**

#### **Do not use**

- more than 1 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 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 or 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 ask 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 breast feeding**

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 1-800-222-1222 right away.

**Directions****adults and children 12 years of age and over:**

- clean and dry affected area
- carefully remove backing from patch starting at the corner
- Apply sticky side of patch to affected area.
- Use one patch for up to 12 hours.
- Discard patch after single use

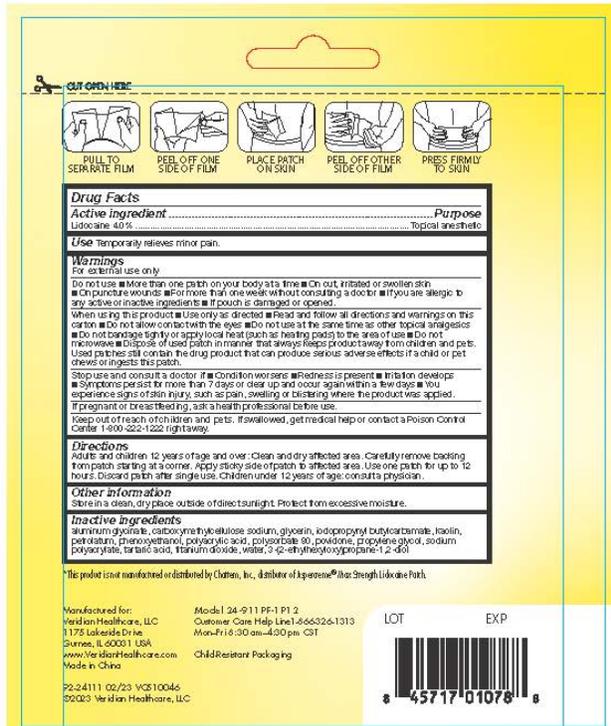
**children under 12 years or age: consult a physician****Other Information**

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

**Inactive Ingredients**

aluminum glycinate, carboxymethylcellulose sodium, glycerin, iodopropynyl butylcarbamate, kaolin, petrolatum, phenoxyethanol, polyacrylic acid, polysorbate 80, povidone, propylene glycol, sodium polyacrylate, tartaric acid, titanium dioxide, water, 3-(2-ethylhexyloxy)propane-1,2-diol

**TheraCare Pain Relieving Patch with Lidocaine**



## Theracare Pain Relieving Patch with Lidocaine

lidocaine patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71101-918
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>TARTARIC ACID</b> (UNII: W4888119H)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>POLYACRYLIC ACID (8000 MW)</b> (UNII: 73861X4K5F)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>DIHYDROXYALUMINUM AMINOACETATE</b> (UNII: DO250MG0W6)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-918-12	1 g in 1 POUCH; Type 0: Not a Combination Product	04/01/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2023	

**Labeler** - Veridian Healthcare (830437997)

### Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.		529128763	manufacture(71101-918)

Revised: 4/2023

Veridian Healthcare