# DRAGON PAIN RELIEF- lidocaine patch Genomma Lab USA, Inc.

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.

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### Dragon Pain Relief Patch Lidocaine 4% 5ct (224)

#### **Active ingredient Purpose**

Lidocaine 4%......Topical anesthetic

#### Use

• temporarily 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
- at the same as other topical analgesics
- on puncture wounds
- for more than one week without consulting a doctor

### When using this product

- use only as directed. Read and follow all directions and wanrings.
- do not allow contact with the eyes
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- discontinue use at least 1 hour before a bath or shower
- dispose of used patch in manner that always keep 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
- symptoms persist for more than 7 days or clear up and occur again within a few days
- irritation develops
- 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.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### **Directions**

### adults and children over 12 years:

- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- use 1 patch for up to 12 hours

#### children 12 years or younger: ask a doctor

Other information

store at room temperature 20-25°C (68-77°F)

### **Inactive ingredients**

alcohol, aluminum glycinate, glycerin, kaolin, methylparaben, polysorbate 80, propylparaben, purified water, sodium polyacrylate, tartaric acid, titanium dioxide

### Distributed by:

Genomma Lab USA, Inc.,

Houston, TX 77027

Made in China



### **DRAGON PAIN RELIEF**

lidocaine patch

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50066-224

**Route of Administration** TOPICAL

## **Active Ingredient/Active Moiety**

Ingredient Name		<b>Basis of Strength</b>	Strength
I	LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg

### **Inactive Ingredients**

Ingredient Name	Strength
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TARTARIC ACID (UNII: W48881119H)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

WATER (UNII: 059QF0KO0R)

# **Packaging**

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-224- 05	5 in 1 CARTON	01/18/2019	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

### **Marketing Information**

Marketing information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	01/18/2019		

# Labeler - Genomma Lab USA, Inc. (832323534)

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