

## **CVS HEALTH LIDOCAINE PAIN-RELIEVING- lidocaine NATURAL ESSENTIALS, 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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### **Drug Facts**

#### **Active ingredient**

Lidocaine 4%

#### **Purpose**

Topical Analgesic

#### **Use**

For the temporary relief of pain.

#### **Warnings**

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

##### **Do not use**

- more than 1 patch on your body at a time or on cut, irritated or swollen skin
- 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 warnings on this carton.
- Do not use more than one patch in an 8 hour period. Maximum 3 patches per day.
- Rare cases of serious burns have been reported with products of this type
- Do not apply to wounds or damaged, broken or irritated skin
- Do not allow contact with the eyes and mucous membranes
- Do not bandage tightly or apply local heat (such as heating pads) to the area of use
- Do not use at the same time as other topical analgesics
- Dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug products that can produce serious adverse effects if a child or pet chews or ingests this patch
- **NOTE:** patches may not adhere as well to all individuals, skin types, or certain parts of the body.

##### **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 physician before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions**

- **Adults/children 12 years and older**
- 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 completely to apply patch to affected area
- once applied, press firmly and rub on all sides and center of patch to help adhesive adhere to skin
- do not remove patch and reapply, this will result in the patch not sticking avoid strenuous exercise while wearing patch, this will result in patch not sticking
- do not use more than one patch in an 8 hour period.

**Children 12 years or younger:** ask a doctor.

## **Other information**

Store at room temperature - do not exceed 86° Fahrenheit, 30° Celsius.

## **Inactive ingredients**

aluminum glycinate, glycerin, kaolin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol, propylparaben, povidone, sodium polyacrylate, tartaric acid, titanium dioxide, water

## **Principal Display Panel - Small Patch Label**

### **CUT OPEN POUCH AND REMOVE PATCH**

### **CVS**

Health®

Compare to the active ingredient in  
Salonpas® 4% Lidocaine Gel Patch\*

## **MAXIMUM STRENGTH**

## Lidocaine concentration without a prescription<sup>†</sup>

### Lidocaine Pain-Relieving Patch

#### LIDOCAINE 4% GEL

#### Desensitizes aggravated nerves

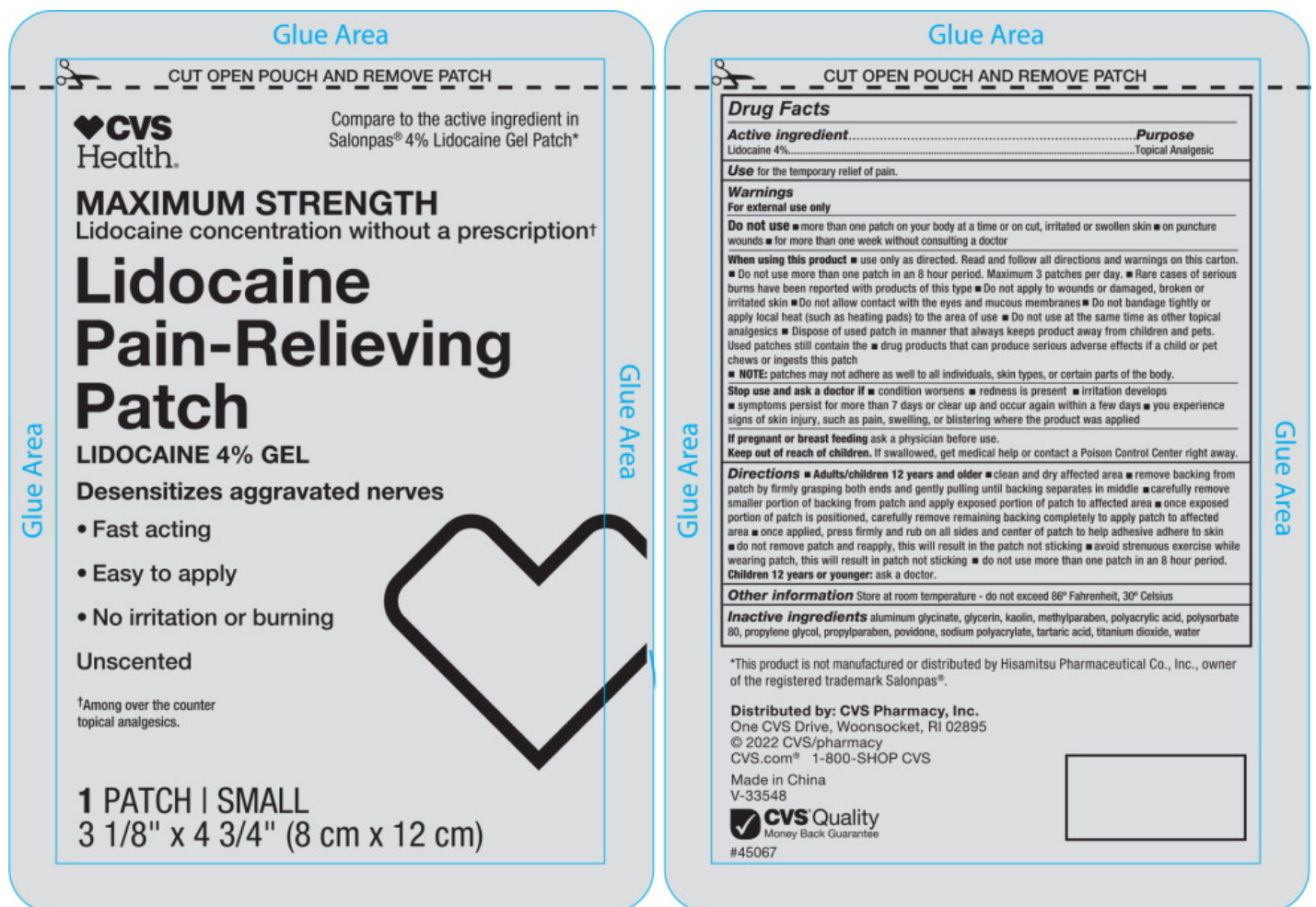
- Fast acting
- Easy to apply
- No irritation or burning

#### Unscented

<sup>†</sup>Among over the counter  
topical analgesics.

1 PATCH | SMALL

3 1/8" x 4 3/4" (8 cm x 12 cm)



## Principal Display Panel - Medium Patch Label

CUT OPEN POUCH AND REMOVE PATCH

**CVS**

Health®

Compare to the active ingredient in  
Salonpas® 4% Lidocaine Gel Patch\*

**MAXIMUM STRENGTH**

**Lidocaine concentration without a prescription<sup>†</sup>**

**Lidocaine  
Pain-Relieving  
Patch**

**LIDOCAINE 4% GEL**

**Desensitizes aggravated nerves**

- **Fast acting**
- **Easy to apply**
- **No irritation or burning**

**Unscented**

**<sup>†</sup>Among over the counter  
topical analgesics.**

**1 PATCH | MEDIUM**

**3 15/16" x 5 1/2" (10 cm x 14 cm)**



## Principal Display Panel - X Large Patch Label

**CUT OPEN POUCH AND REMOVE PATCH**

**CVS**  
Health®

Compare to the active ingredient in  
Salonpas® 4% Lidocaine Gel Patch\*

**MAXIMUM STRENGTH**

**Lidocaine concentration without a prescription†**

**Lidocaine  
Pain-Relieving  
Patch**

**LIDOCAINE 4% GEL**

**Desensitizes aggravated nerves**

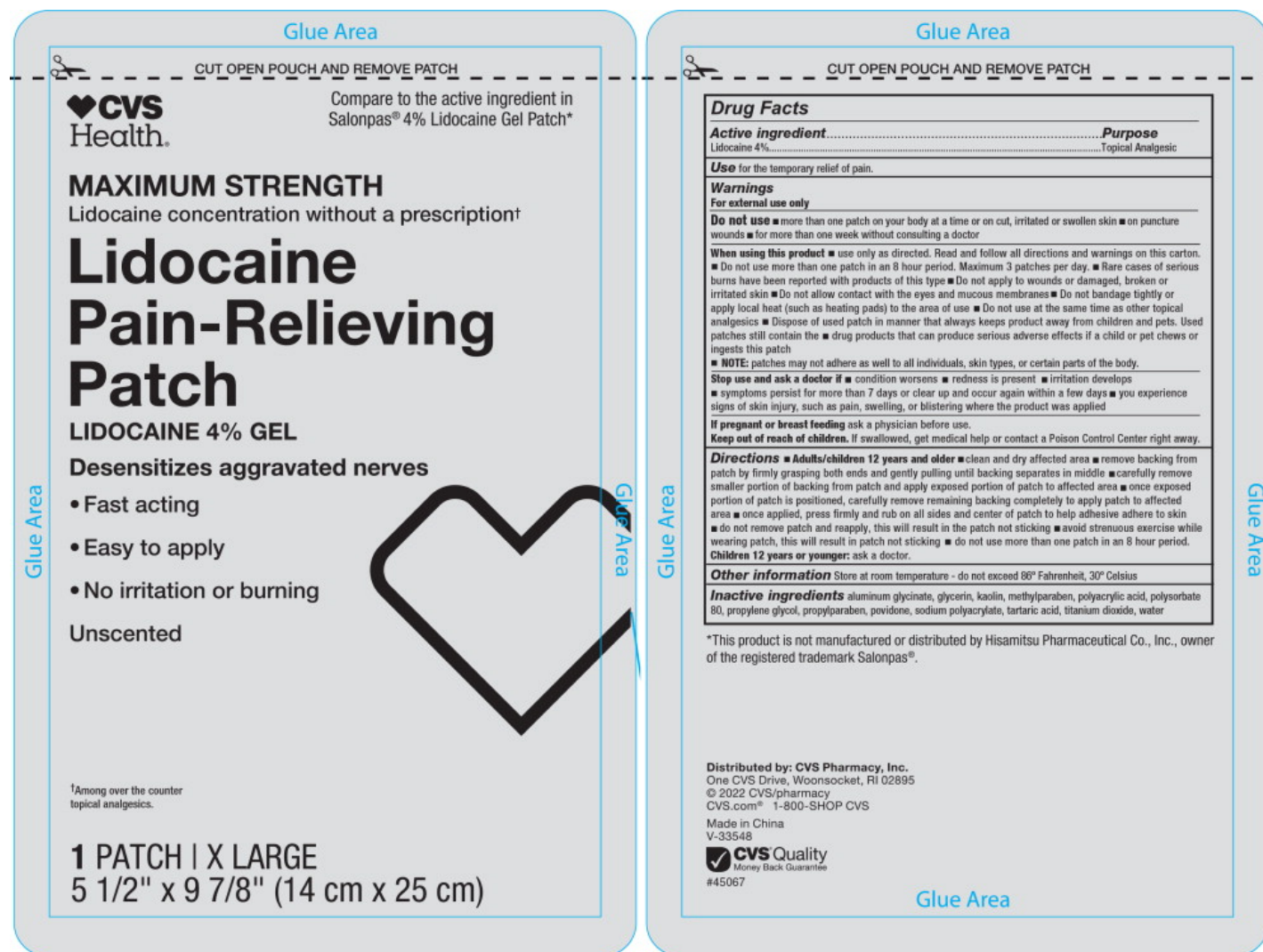
- **Fast acting**
- **Easy to apply**
- **No irritation or burning**

**Unscented**

†Among over the counter  
topical analgesics.

1 PATCH | X LARGE

5 1/2" x 9 7/8" (14 cm x 25 cm)



## Principal Display Panel - Carton Label

**CVS**  
Health®

Compare to the active  
ingredients in Salonpas®  
4% Lidocaine Gel Patch\*

**MAXIMUM STRENGTH**

**Lidocaine concentration  
without a prescription†**

**Lidocaine  
Pain-Relieving**





# CVS HEALTH LIDOCAINE PAIN-RELIEVING

lidocaine kit

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-450
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-450-06	1 in 1 CARTON; Type 0: Not a Combination Product	06/02/2020	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 PATCH	14 g
Part 2	2 PATCH	22 g
Part 3	2 PATCH	46 g

## Part 1 of 3

# CVS HEALTH LIDOCAINE PAIN-RELIEVING

lidocaine patch

## Product Information

Item Code (Source)	NDC:66902-270
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Route of Administration	TRANSDERMAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	40 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	



<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-270-01	2 in 1 NOT APPLICABLE		
1		7 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	06/02/2020	

## Part 2 of 3

## CVS HEALTH LIDOCAINE PAIN-RELIEVING

lidocaine patch

## Product Information

<b>Item Code (Source)</b>	NDC:66902-270
<b>Route of Administration</b>	TRANS DERMAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Lidocaine</b> (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	40 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS</b> (UNII: 1K713C615K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYACRYLIC ACID (8000 MW)</b> (UNII: 73861X4K5F)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-270-02	2 in 1 NOT APPLICABLE		
1		11 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	06/02/2020	

## Part 3 of 3

## CVS HEALTH LIDOCAINE PAIN-RELIEVING

lidocaine patch

## Product Information

<b>Item Code (Source)</b>	NDC:66902-270
<b>Route of Administration</b>	TRANS DERMAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Lidocaine</b> (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	40 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS</b> (UNII: 1K713C615K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYACRYLIC ACID (8000 MW)</b> (UNII: 73861X4K5F)	

<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-270-03	2 in 1 NOT APPLICABLE		
1		23 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	06/02/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/02/2020	

**Labeler -** NATURAL ESSENTIALS, INC. (947484713)

## Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech, Co., Ltd.		529128763	MANUFACTURE(66902-450, 66902-270)

Revised: 1/2023

NATURAL ESSENTIALS, INC.