

**ASSURED PAIN RELIEF- lidocaine**  
**Foshan Aqua Gel Biotech Co., Ltd.,**

*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 ingredients**

Lidocaine 4%

**Purpose**

Topical analgesic

**Uses** temporarily relieves minor pain

**Warnings for external use only.**

**Do not use**

•more than one patch on your body at a time or on cut •on wounds or damaged skin •with a heating pad

**When using this product**

•avoid contact with eyes, mucous membranes or rashes •use only as directed •do not bandage tightly  
•do not use at the same time as other topical analgesics •dispose of used patch in a manner that always keeps products away from children and pets

**Stop use and ask a doctor if**

•you experience signs of skin injury, such as pain, swelling or blistering where product was applied  
•symptoms persist for more than 7

days or clear up and occur again within a few days •condition worsens •redness is present •irritation develops

**Keep out of reach of children.** On case of accidental ingestion, get medical help or contact a Poison Control Center right away.

**Pregnancy.breast-feeding warning.** If pregnant or breast-feeding, ask a health professional before use.

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

•Clean and dry affected area •Remove film from patch and apply to the skin (see package for instructions)

•Apply to affected area not more than 3 to 4 times daily •Remove patch from the skin after at most 8 hours of application

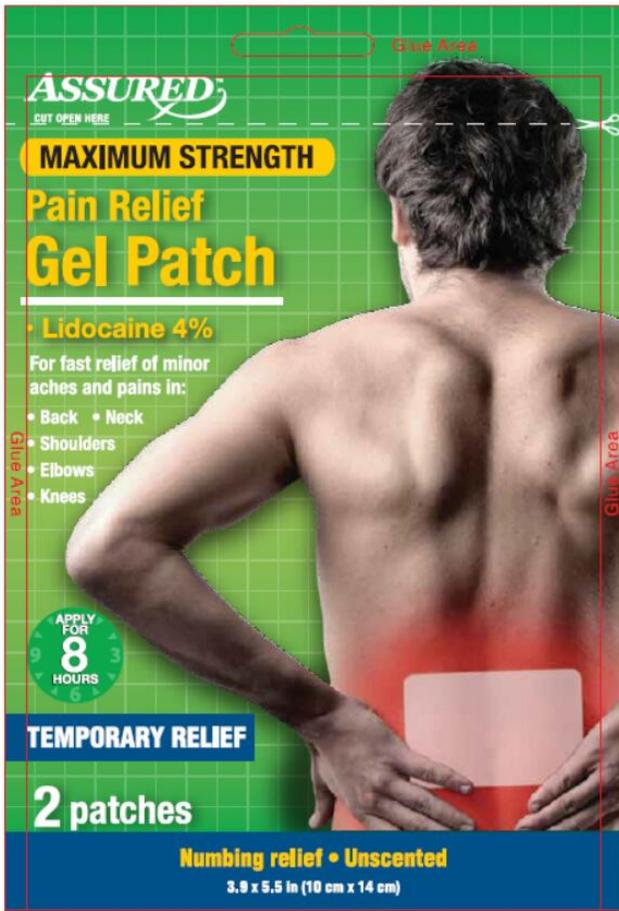
Children under 12 years of age: consult a physician

**Other information**

•Store at room temperature 58° - 86° F (15° - 30° C). Avoid storing product in direct sunlight •Protect product from excessive moisture

**Inactive ingredients** DIHYDROXYALUMINUM AMINOACETATE, GLYCERIN, KAOLIN, METHYLPARABEN, PROPYLPARABEN, PROPYLENE GLYCOL,

PVP, POLYACRYLIC ACID, POLYSORBATE 80, SODIUM POLYACRYLATE, TITANIUM DIOXIDE, TARTARIC ACID, WATER



20.5CM



## ASSURED PAIN RELIEF

lidocaine kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 159-101
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69 159-101-01	1 in 1 KIT	08/20/2017	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	7 PATCH	100 g
Part 2		1

### Part 1 of 2

## ASSURED PAIN RELIEF

lidocaine gel

**Product Information****Item Code (Source)** NDC:69 159-100**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
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69 159-100-01	15 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		

**Part 2 of 2****ASSURED PAIN RELIEF**

pack, hot or cold, disposable

**Product Information****Item Code (Source)** GS1:30707387763634

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	IMD		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/20/2017	

**Labeler** - Foshan Aqua Gel Biotech Co., Ltd., (529128763)

## Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(69159-101) , pack(69159-101) , label(69159-101)

Revised: 9/2017

Foshan Aqua Gel Biotech Co., Ltd.,