ASSURED PAIN RELIEF- lidocaine gel
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.

Drug Facts

Active ingredients

Lidocaine 4%

Purpose

Topical analgesic

Uses temporarily releives 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 pregant 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). Acoid 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

CUT OPEN HERE

ASSURED™

Pain Relief
Gel Patch

For fast relief of minor aches and pains.

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■ 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

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Directions Adults and children 12 years of age and over:
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Other information
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Inactive ingredients dihydroxyaluminum aminoacetate, glycerin, kaolin, methylparaben, propylparaben, propylene glycol, PVP, polyacrylic acid, polysorbate 80, sodium polyacrylate, titanium dioxide, tartaric acid, water

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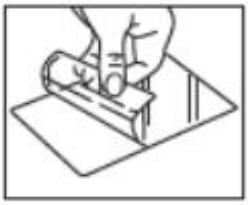
Cut the envelope along the dotted line. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. Safely discard the remaining unused pieces of cut patches where children and pets cannot get to them.



Remove the transparent release liner (clear plastic backing) before application of patch to the skin.

Apply immediately after removal from the protective envelope.

Place on affected area and press patch thoroughly.

Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

265050 1710
DISTRIBUTED BY
GREENBRIER
INTERNATIONAL, INC.
500 VOLVO PARKWAY,
CHESAPEAKE, VA 23320
MADE IN CHINA

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Glue Area

Glue Area

ASSURED PAIN RELIEF

lidocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69159-100
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (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:69159-100-01	15 g in 1 PATCH; Type 0: Not a Combination Product	08/20/2017	

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(69159-100)

Revised: 9/2017 Foshan Aqua Gel Biotech Co., Ltd.,