LIDOCAINE PAIN RELIEF PATCH- lidocaine and menthol, unspecified form patch
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.

Lidocaine Pain Relief Patch

Active Ingredients

Lidocaine 4%

Menthol 1%

Purpose:

Topical anesthetic

Topical anesthetic

Uses:

For the temporary relief of pain.

Warnings

For external use only
Avoid contact with eyes.

Do not use

- if you are allergic to any active and inactive ingredients listed in this patch
- if pouch is damaged or opened
- on raw surfaces or blistered areas, open wounds, or on damaged, cut, irriated or sensitive skin
- 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 package
- do not allow contact with eyes or 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
- do not reuse patch
- 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

- conditions worsens
- rash, itching or skin irritation develops
- symptoms persist for more than 7 days or clear up and occurs 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

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children over 12 years of age:

- clean and dry affected area
- strip off the clear protective film and place adhesive patch over affected area
- leave in place for up to 8 hours
- wash hands thoroughly after applying or removing patch.

Children under 12 years: ask a doctor before use.

Other Information

Store below 25°C (77°F). Avoid direct sunilght.

Inactive Ingredients:

dihydroxyaluminum aminoacetate, glycerin,kaolin,methylparaben,polyacrylic acid,polysorbate 80,propylene glycol,propylparaben, povidone,sodium polyacrylate, tartaric acid,tatanium dioxide,water.

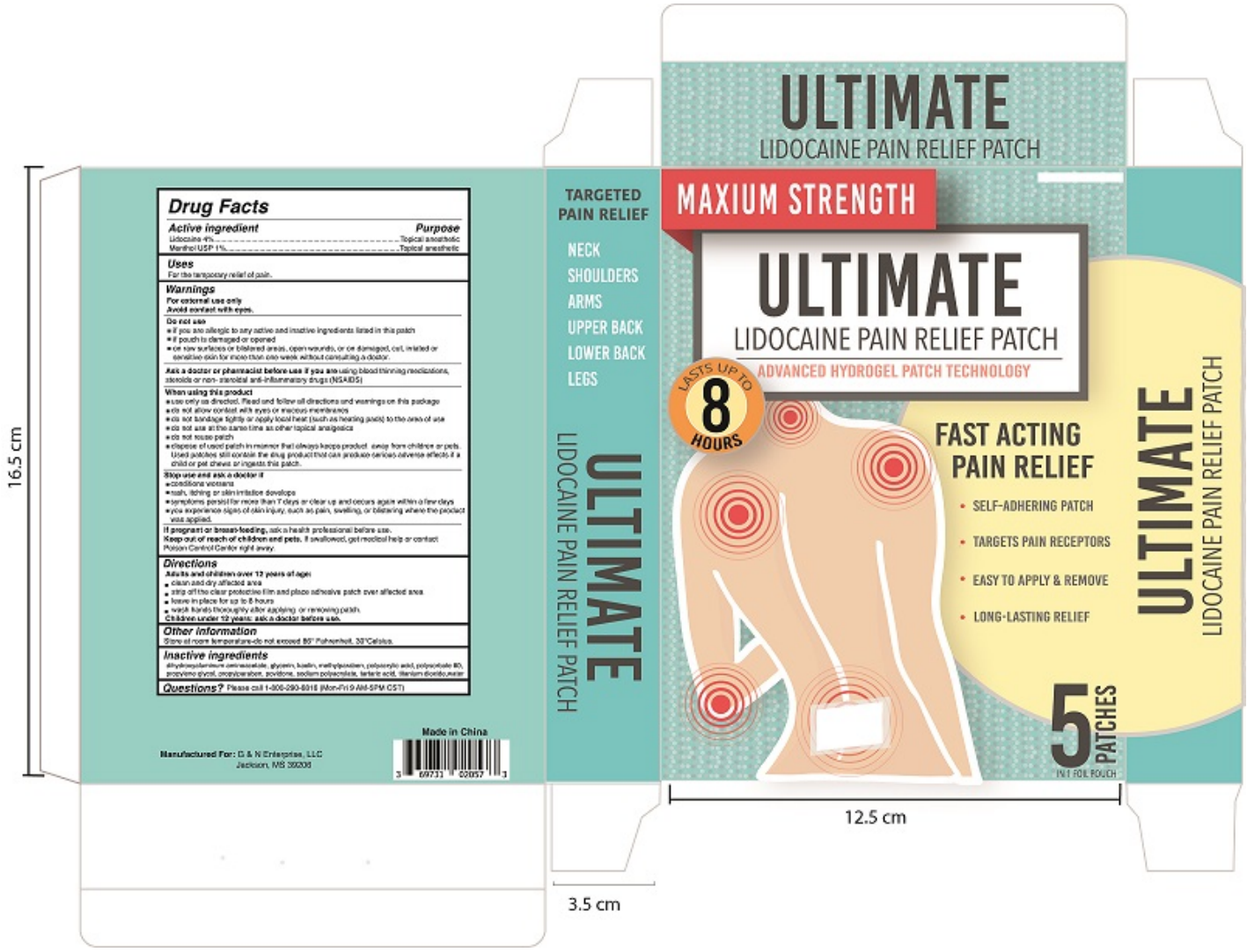
Questions or Comments?

Please call 1-800-290-6816 (Mon-Fri 9AM-5PM CST)

Dosage and Administration

Lidocaine Pain Relief Patch contains 4% Lidocaine and 1% Menthol.

Lidocaine Pain Relief Patch



LIDOCAINE PAIN RELIEF PATCH

lidocaine and menthol, unspecified form patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69159-920
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	

GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color		**Score**	
Shape	RECTANGLE	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69159-920-05	1 in 1 CARTON	09/01/2016	
1		5 in 1 POUCH		
1		9 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	09/01/2016	

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

Revised: 11/2017 Foshan Aqua Gel Biotech Co.,Ltd.