ULTIMATE TOPICAL PAIN RELIEF PATCH- capsaicin 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.

Ultimate Topical Pain Relief Patch

Active Ingredients

Menthol 5.00%

Capsaicin 0.0375%

Purpose:

External Analgesic/Counterirritant

External Analgesic/Counterirritant

Uses:

Temporarily relieves minor aches and muscle pain associated with simple back ache, arthritis, strains and sprains. Use only as directed.

Warnings

- For external useonly.
- Avoid contact with eyes and mucous membranes.
- Do not use on wounds or damaged skin.
- Do not cover with bandage.
- Do not use if you are allergic to Menthol.
- Consult physician for use on children under 12.

Stop use and ask a doctor if

conditions worsen, if symptoms persist for more than 7 days or clear up and occur again with a few days, or if a rash,

itching or excessive skin irritation occurs.

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 12 and over apply to affected area; change patch 1 to 2 times daily
- Children under 12 years: Consult physician before use.

Other Information

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

Inactive Ingredients:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Diazolidinyl Urea, EDTA Disodium ,Glycerin, Iodopropynyl Butylcarbamate, Methylparaben, Polysorbate 80, Propylparaben, Sodium Polyacrylate, and Water.

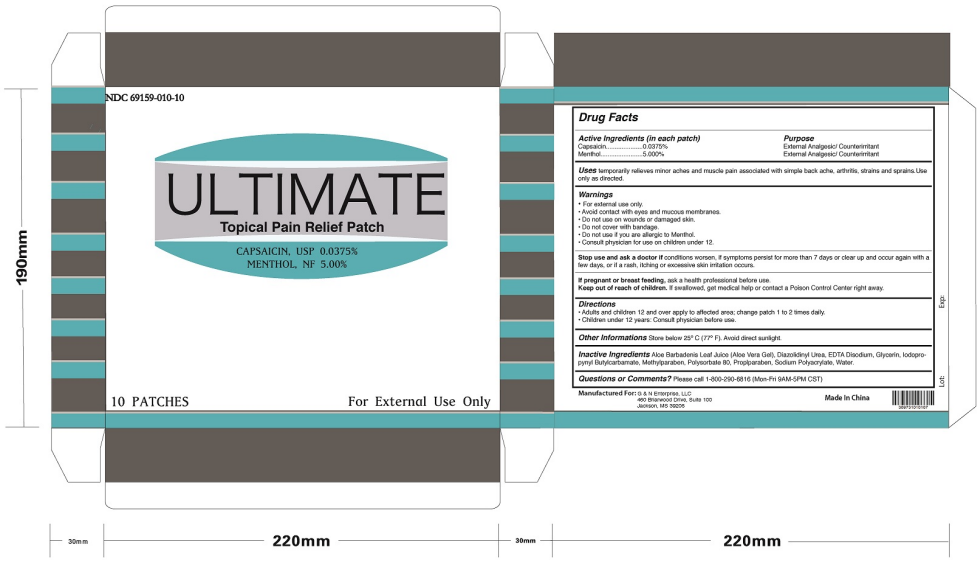
Questions or Comments?

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

Dosage and Administration

Ultimate Topical Pain Relief Patch contains 0.0375% capsaicin and 5.00% menthol

Ultimate Topical Pain Relief Patch



ULTIMATE TOPICAL PAIN RELIEF PATCH

capsaicin and menthol, unspecified form patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69159-910
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	5 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0375 g

CAPSAICIN (UNII: 30V044R1ZM) (CAPSAICIN - UNII:30V044R1ZM)	CAPSAICIN	in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69159-910-05	1 in 1 CARTON	05/01/2016	
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	05/01/2016	

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

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