LIDOTHAL RELIEF- menthol, lidocaine patch
19 And Pacific, Llc

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 Ingredient

Menthol 1.00%

Lidocaine 4.00%

Purpose

External analgesic

External analgesic

Uses:

For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, strains,

bruises and sprains

Warnings:

- For external use only
- Avoid contact with eyes
- Do not apply to open wounds or damages skin
- If symptoms persist for more than seven days, discontinue use and consult physician
- Keep out of reach of children. If swallowed, consult physician.
- Do not bandage tightly
- If pregnant or breast feeding, contact physician prior to use

Keep out of reach of children. If swallowed, consult physician.

Directions:

- Clean and dry affected area
- Remove patch from backing and apply to affected area. Apply directly to affected area.
- Use only on patch at a time, and a maximum of four patches per day.
- Leave patch of affected area for up to eight hours.
- Do not use patches for more than five consecutive days
- Children under 12 should consult a physician prior to use.

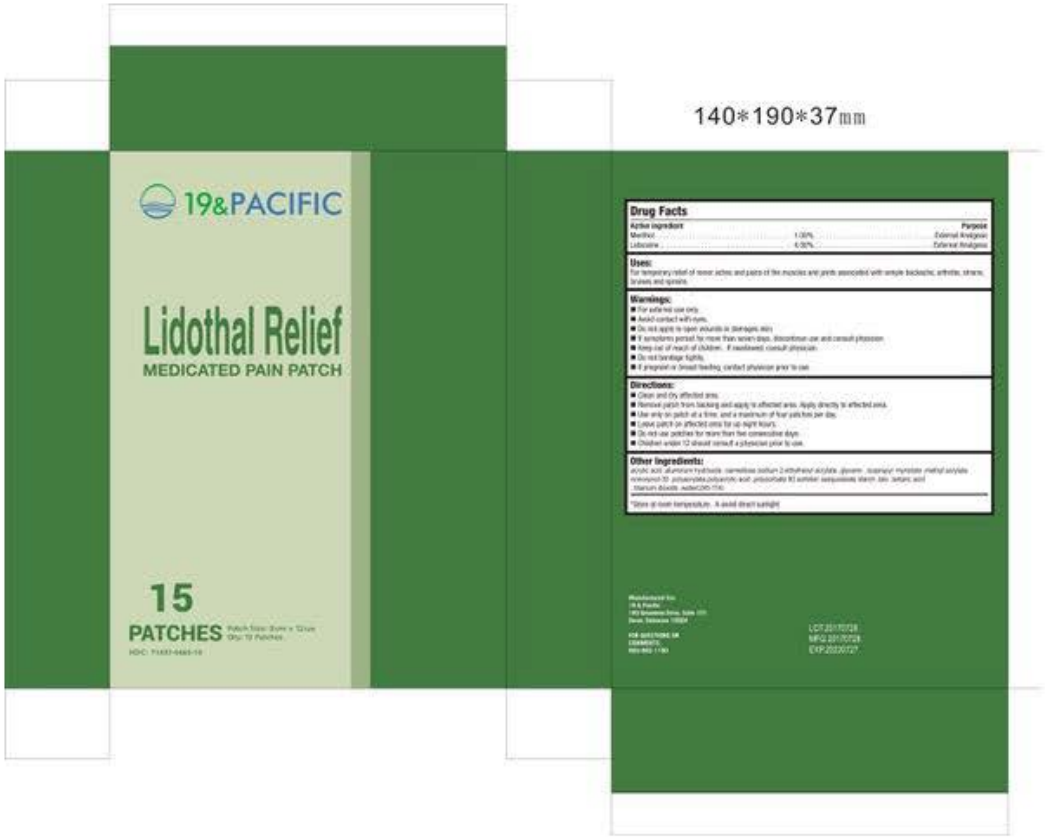
Store at room temperature. Avoid direct sunlight.

Other Ingredients:

acrylic acid ,aluminum hydroxide . carmellose sodium 2-ethylexyl acrylate glycerin . isopropyl myristate .methyl acrylate

nonoxynol-30 .poluacrylate.polyacrylic acid .polysorbate 80 sorbitan sesquioleate strach .talc .tartaric acid

.titanium dioxide .water(254-114)



LIDOTHAL RELIEF

menthol, lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71437-463
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71437-463-15	15 in 1 BOX	07/31/2017	
1		8.5 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	07/31/2017	

Labeler - 19 And Pacific, Llc (080619263)

Establishment

Name	Address	ID/FEI	Business Operations
19 And Pacific, Llc		080619263	label(71437-463) , pack(71437-463)