

HOT AND COLD LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF- lidocaine and menthol patch
INTERMED

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.

Hot and Cold Lidocaine with Menthol Patch- Bulk

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Lidocaine 4 % (240 mg)	Topical analgesic
Menthol 1% (60 mg)	Topical analgesic

Uses

Temporarily relieves minor pain associated with: arthritis, simple backache, bursitis, tendonitis, muscle strains, sprains & bruises.

Warnings

For external use only.

Do not use if you are allergic or sensitive to lidocaine or menthol. Do not use if pouch is damaged or opened.

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not apply to open wounds or sensitive skin
- do not bandage tightly or use a heating pad

Stop use and ask a doctor if

- excessive redness or irritation is present
- condition worsens
- pain persists for more than 7 days
- symptoms clear up and occur again within a few days

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: apply patch to affected area for a maximum of 12 hours. Do not use more than 1 patch every 24 hours.
- children: consult your physician
- remove protective film, gently apply to affected area.

Inactive Ingredients

Dihydroxyaluminium aminoacetate, disodium EDTA, glycerin, methylparaben, polyvinyl alcohol, propyl paraben, propylene glycol, purified water, sodium carboxymethyl cellulose, sodium polyacrylate, tartaric acid, titanium dioxide

Qty : 100x5's = 500 Patches

Case No :

MAXIMUM STRENGTH**
HOT & COLD
 4% LIDOCAINE PAIN RELIEVING PATCH
 WITH MENTHOL

Active Ingredients :

Lidocaine.....4%,Menthol.....1%

Storage : Store product at room temperature, do not exceed 30°C(86°F)
 Protect product from direct sunlight and excessive moisture

Batch No. :	Gross Weight :
Mfg. Date :	Net weight :
Exp. Date :	

Code : TN/DRUGS/22/1999
 Manufacturer Name : **INTERMED**
 Manufacturer Address : No 4, GK Industrial Estate,
 Arcot Road, Porur, Chennai-600116
 INDIA
 Manufacturer Labeller Code : 71811

Consignee:
 Velocity Pharma LLC,
 Farmingdale, NY 11735
 Consignee Labeller Code : 76168



HOT AND COLD LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF

lidocaine and menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71811-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	240 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	60 mg

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	

TARTARIC ACID (UNII: W48881119H)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71811-002-05	500 in 1 CASE	11/22/2019	
1		1 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	11/22/2019	

Labeler - INTERMED (676244169)

Revised: 11/2019

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