HOT AND COLD LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF- lidocaine and menthol patch
Velocity Pharma 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.

Hot and Cold Lidocaine with Menthol Patch- RA

Drug Facts

Active Ingredients	***Purpose***
Lidocaine 4 %	Topical analgesic
Menthol 1%	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, Glycerol, Kaolin, Methylparaben, Polyacrylic acid, Propylene glycol, Propylparaben, PVP, Sodium polyacrylate, Tartaric acidm Titanium diocide, Tween 80, Water

PRINCIPAL DISPLAY PANEL

CONTAINS LIDOCAINE with Menthol- RA

PAIN RELIEF PATCH

5TOPICAL PATCHES PER BOX

HOT AND COLD LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF

lidocaine and menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-304
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg

Inactive Ingredients	
Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0KO0R)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-304-11	5 in 1 CARTON	05/25/2017	
1		1 in 1 POUCH; 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	03/03/2017	

Labeler - Velocity Pharma LLC (962198409)

Registrant - Velocity Pharma LLC (962198409)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(76168-304)

Revised: 9/2017 Velocity Pharma LLC