VENIA PATCH PREMIUM PAIN PATCH- menthol, lidocaine patch Alivio Medical Products, 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 Ingredients

Menthol 4 %

Lidocaine 4 %

Purpose

Topical anesthetic

Topical anesthetic

Uses:

For the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness

Warnings:

- -Only for external use. Use only as directed or by a health professional.
- -Do not use: on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.
- -Do not cover with bandage.
- -Keep out of reach of children. Consult physician for children under 12.
- -Consult your physician: if pregnant or pain persists or worsens.

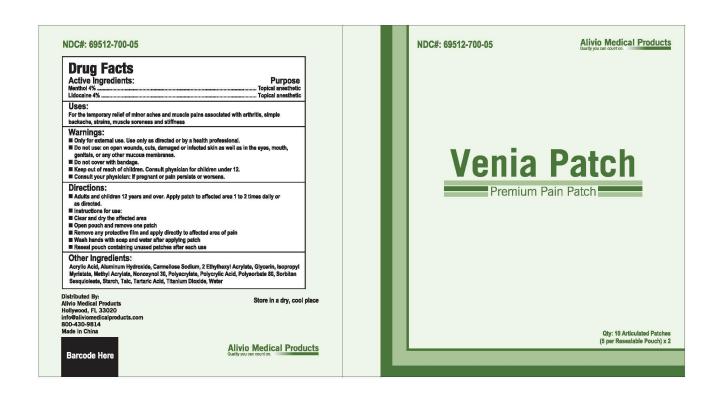
Directions:

- -Adults and children 12 years and over. Apply patch to affected area 1 to 2 times daily or as directed.
- -Instructions for use:
- -Clear and dry the affected area
- -Open pouch and remove one patch
- -Remove any protective film and apply directly to affected area of pain
- -Wash hands with soap and water after applying patch
- -Reseal pouch containing unused patches after each use

Keep out of reach of children. Consult physician for children under 12

Other ingredients:

Acrylic Acid, Aluminum Hydroxide, Carmellose Sodium, 2 Ethylhexyl Acrylate, Glycerin, Isopropyl Myristate, Methyl Acrylate, Nonoxynol 30, Polyacrylate, Polyacrylic Acid, Polysorbate 80, Sorbitan Sesquioleate, Starch, Talc, Tartaric Acid, Titanium Dioxide, Water



VENIA PATCH PREMIUM PAIN PATCH

menthol, lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69512-700
Route of Administration	TOPICAL		

A	ctive Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength
	ENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - NII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	4 mg in 100 g
LI	IDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE	4 mg in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
ACRYLIC ACID (UNII: J94PBK7X8S)		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)		
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
METHYL ACRYLATE (UNII: WC487PR91H)		

NONOXYNOL-30 (UNII: JJX07DG188)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W48881119 H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69512-700-05	10 in 1 BOX		
1	1 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	08/01/2015	

Labeler - Alivio Medical Products, LLC (079670828)

Revised: 8/2015 Alivio Medical Products, LLC