

ALIVIO MEDICATED PAIN- menthol, capsaicin 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.

Alivio Medicated Pain Patch

Drug Facts

Active ingredient

Menthol 5.00%

Capsacin 0.03%

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.
- bandage tightly
- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children

If swallowed, consult physician.

If pregnant or breast feeding,

contact physician prior to use.

Directions:

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

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 (245-114)

Store

at room temperature. Avoid direct sunlight

Package Label

Alivio Patch

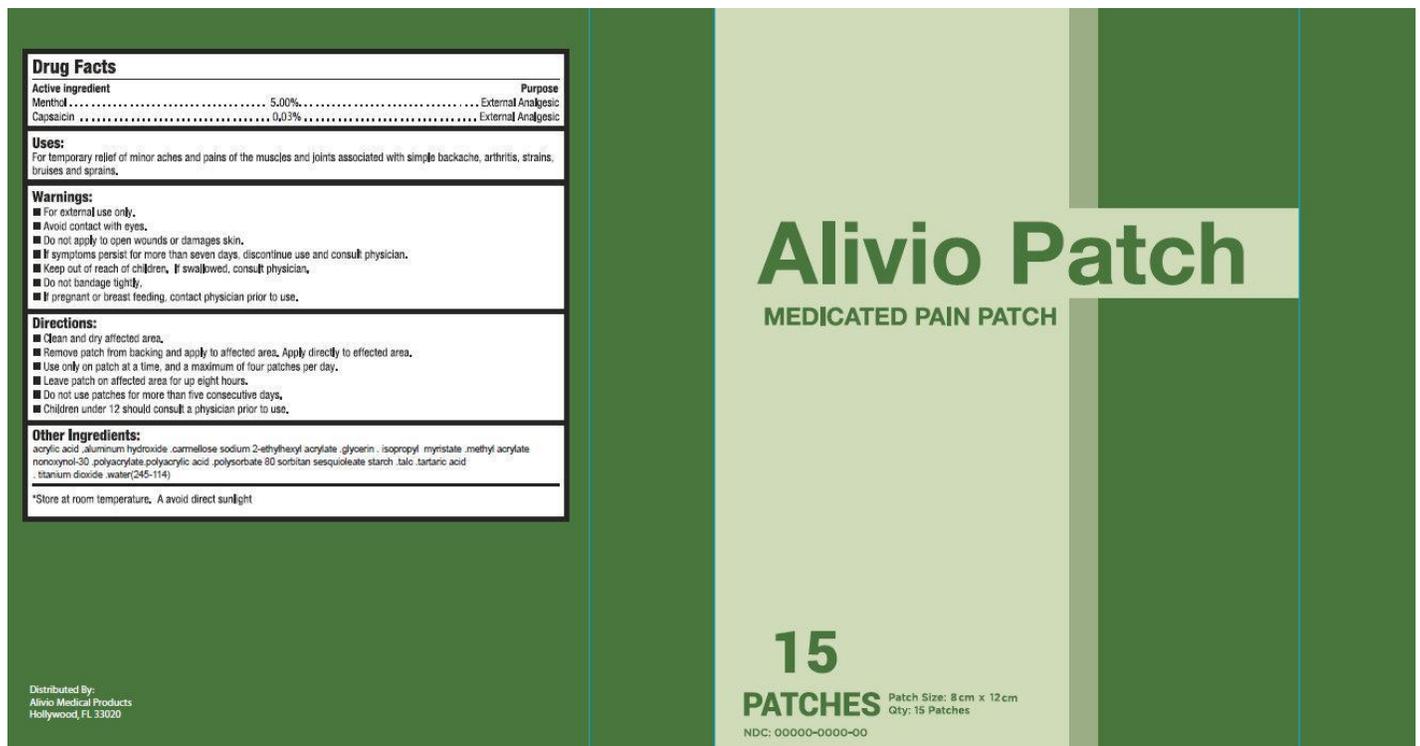
MEDICATED PAIN PATCH

15 PATCHES

Distributed by:

Alivio Medical Products

Hollywood, FL 33020



ALIVIO MEDICATED PAIN

menthol, capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69512-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.03 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDRO XIDE (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:69512-001-01	15 in 1 BOX		
1		8.5 g in 1 PATCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/21/2015	

Labeler - Alivio Medical Products, LLC (079670828)**Establishment**

Name	Address	ID/FEI	Business Operations
Zhejiang Bangli Medical Products Co.,Ltd		421295875	manufacture(69512-001)

Revised: 1/2015

Alivio Medical Products, LLC