

FESI- menthol, capsaicin patch
API SOLUTIONS INC.

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.

FESI Patch

ACTIVE INGREDIENTS

Menthol	5.00%
Capsaicin	0.05%

PURPOSE

Topical Analgesic
Topical Analgesic

USES

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

WARNINGS

For external use only.

When using this product

- use only as directed

do not use

- on, and avoid contact with face, scalp, eyes, mouth, and mucous membranes
- do not use on wounds or damaged or sensitive skin
- do not use in combination with any external heat source (heating pad, etc.) or for 1 hour before or after bathing or showering
- do not use in combination with any compression (bandage, wrap, brace, stocking, sock, or similar device or garment)
- do not use in combination with any other external analgesic products

Stop use and ask a doctor if

- excessive redness, burning, swelling, irritation, or discomfort develops in the skin, eyes, mouth or mucous membranes
- 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 doctor before use.

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away

DIRECTIONS

- Adults and children 16 years and over
- apply directly to affected area of pain
- change patch 1 to 2 times daily, or as directed by a doctor
- children under 16 years, ask a doctor before using

how to apply:

- clean and dry affected area - tear open pouch and remove one patch
- remove protective film and apply directly to affected area of pain
- reseal pouch containing unused patches after each use
- **wash hands with soap and water after applying**

OTHER INGREDIENTS:

Aqua (Deionized Water), Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Diazolidinyl Urea, Glycerine, Iodopronyl Butylcabamate, Methylparaben, Polysorbate 80, Propylparaben, Sodium Polyacrylate, Tetrasodium EDTA.

Distributed by:

A.P.I SOLUTIONS

Daphen, AL 36526

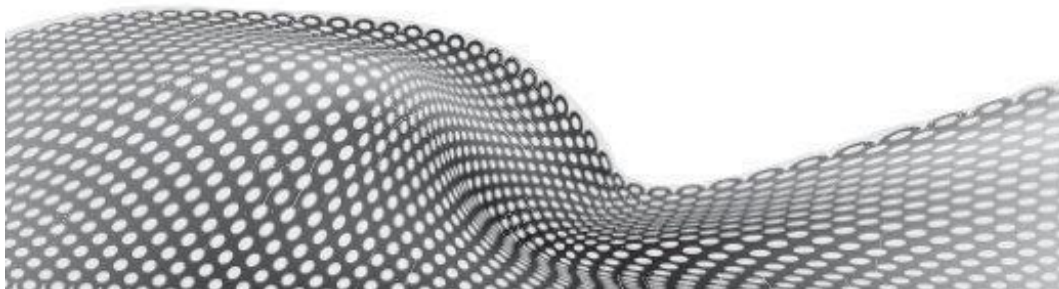
For Questions or Comments Please Call 855-878-1489

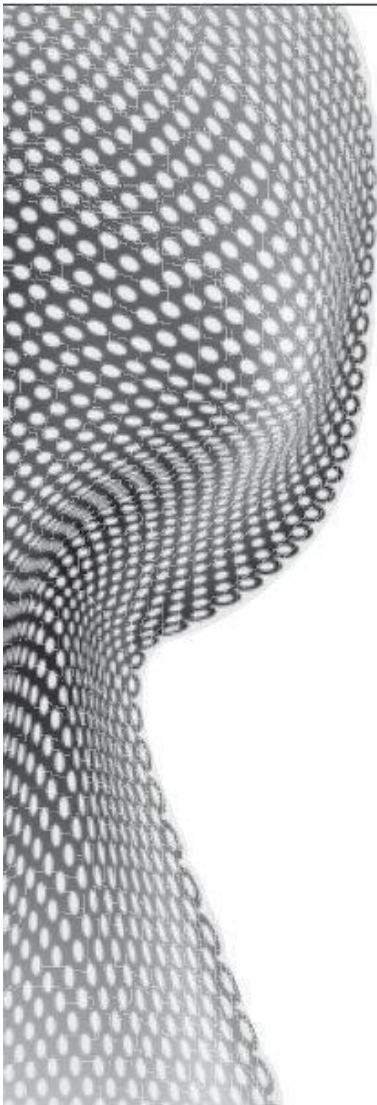
FESI Pain Relief Patch, 15 Count (46144-941-15)

Fesi

patch

Topical Analgesic Patch – Menthol 5%/Capsaicin 0.05%
Qty: 15 Patches





Fesi patch

DRUG FACTS:

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FESI

menthol, capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46 144-941
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	0.05 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46144-941-15	15 in 1 BOX	10/13/2014	
1		15 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	10/13/2014	

Labeler - APISOLUTIONS INC. (831870824)

Revised: 12/2017

API SOLUTIONS INC.