

LEVATIO PATCH - menthol, capsaicin patch

Alivio Medical Products, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Drug Facts

Active Ingredient

Menthol 5.00 %

Capsaicin 0.03 %

Other Ingredients:

acrylic acid ,aluminum hydroxide . carmellose sodium 2-ethylexyl acrylate glycerin . isopropyl myristate .methyl acrylate

nonoxynol-30 .poluacrylate.polyacrylic acid .polysorbate 80 sorbitan sesquioleate strach .talc .tartaric acid

.titanium dioxide .water(254-114)

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
- If symptoms persist for more than seven days, discontinue use and consult physician
- Keep out of reach of children. If swallowed, consult physician.
- Do not bandage tightly
- 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 affected area.
- Use only on patch at a time, and a maximum of four patches per day.
- Leave patch of affected area for up to eight hours.
- Do not use patches for more than five consecutive days
- Children under 12 should consult a physician prior to use.

Store at room temperature. Avoid direct sunlight.

Leveatio - menthol and capsaicin patch

Levatio Patch

Description

Levatio Patch contains capsaicin and menthol in a localized topical dermal delivery system. The capsaicin in Levatio is a synthetic equivalent of the naturally occurring compound found in chili peppers. Capsaicin is soluble in alcohol, acetone, and ethyl acetate and very slightly soluble in water.

The menthol is slightly soluble in water.

Levatio is a single-use patch stored in a foil pouch.

Each Levatio patch is 8 cm x 12 cm and consists of a polyester backing film coated with a drug-containing silicone adhesive formulation, and covered with a removable polyester release liner.

The empirical formula for capsaicin is C₁₈H₂₇NO₃ with a molecular weight of 305.42. The chemical compound capsaicin [(E)-8-methyl-N-vanillyl-6-nonenamide] is an activating ligand for transient receptor potential vanilloid 1 receptor (TRPV1)

The empirical formula for menthol is C₁₀H₂₀O with a molecular weight of 156.27. The chemical compound menthol [(1R,2S,5R)-2-isopropyl-5-methylcyclohexanol] is an activating ligand for transient receptor potential cation channel subfamily M member 8 (TRPM8).

Each Levatio Patch contains 0.03% capsaicin (0.03 grams of capsaicin per patch) and 5% menthol (5 grams of menthol per patch). The Levatio Patch contains the following inactive ingredients: acrylic acid, aluminum hydroxide, carmellose sodium 2-ethylhexyl acrylate, glycerin, isopropyl myristate, methyl acrylate, nonoxynol-30, polyacrylate, polyacrylic acid, polysorbate 80 sorbitan sesquileate starch, talc, tartaric acid, titanium dioxide, water (245-114).

INDICATIONS AND USAGE

Levatio Patch is indicated for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

Levatio Patch is an external analgesic/counterirritant.

CONTRAINDICATIONS

Levatio Patch is indicated for those patients with a history of hypersensitivity to any of the components of the preparation.

WARNINGS

***FOR EXTERNAL USE ONLY**

***USE ONLY AS DIRECTED**

*AVOID CONTACT WITH EYES AND MUCOUS MEMBRANES,

*DO NOT COVER WITH BANDAGE

*DO NOT USE ON WOUNDS OR DAMAGED SKIN.

*CONSULT PHYSICIAN FOR CHILDREN UNDER 12

DO NOT USE IF YOU ARE ALLERGIC TO MENTHOL.

*STOP USE AND ASK A DOCTOR IF SYMPTOMS PERSIST FOR MORE THAN 7 DAYS OR CLEAR UP AND OCCUR AGAIN WITHIN A FEW DAYS OR RASH, ITCHING OR EXCESSIVE SKIN IRRITATION OCCURS.

*KEEP OUT OF REACH OF CHILDREN.

DOSAGE AND ADMINISTRATION

Levatio Patch contains 0.03% capsaicin and 5.00% menthol. Instructions for use

*Clean and dry affected area

*Cut open pouch and remove pouch

*Remove protective film and apply directly to area of pain

*Apply to affected area not more than 3 times daily

*Wash hands with soap after applying patch

*Reseal pouch containing unused patches

DIRECTIONS

Adults and children 12 years and over - apply to affected area change patch 1 to 2 times daily

Children under 12 years - Consult physician before use

HOW SUPPLIED

Levatio Patch is supplied in 3 re-sealable pouches each containing 5 patches. NDC 69512-010-02

15 Patches per carton

Storage: Store at 20 to 25 C (68 to 77 F)

Avoid direct sunlight

Distributed by: Alivio Medical Products, LLC

Hollywood, FL



 21st Century LABELS & PACKAGING 4061 SW 47 Avenue Fort Lauderdale, FL 33314 Ph: (954) 272-6500 Fax (954) 272-6501 www.21stCenturyLabels.com	Document Info File: Alvo_Medicated_Pain_Patch_15p Size: 11.0622 X 13.937 21c#: PUR 1473 Date: 11-19-14 PROOF: 5	Colors Black 7404 7742 7404 Pattern UV 000 000 000	Label Position Chart 	Customer Approval Please mark all changes clearly and legibly on this proof and E-mail, fax or deliver to 21st Century Labels. Patch Count: 5 Material: 16 PF Coating: Pattern UV Signature: _____ Date: _____
	NOTE: COLOR PROOFS ARE PROVIDED ONLY AS A VISUAL REFERENCE TO THE FINAL PRINTED PIECE. THE COLORS SHOWN ARE ONLY REPRESENTATIONAL, AND ARE NOT INTENDED TO MATCH ACTUAL PRESS COLOR. Providing customer approval, any and all content/art changes are therefore the responsibility of the customer. Please submit approvals to the Art Department at art@21stcenturylabels.com.			

LEVATIO PATCH

menthol, capsaicin patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69512-010
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
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ACRYLIC ACID (UNII: J94PBK7X8S)
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)
CROSCARMELOSE 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:69512-010-02	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
unapproved drug other		03/01/2015	

Labeler - Alivio Medical Products, LLC (079670828)