

BIOACHES- capsaicin , menthol patch

BIO-SANTEE CHEM

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.

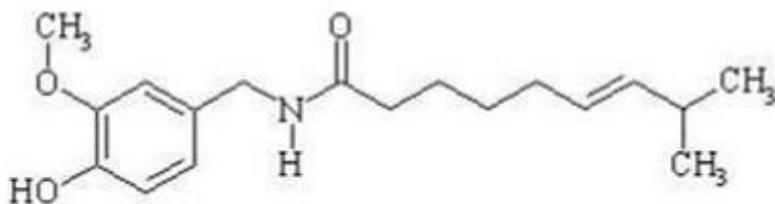
BIOACHES

DESCRIPTION:

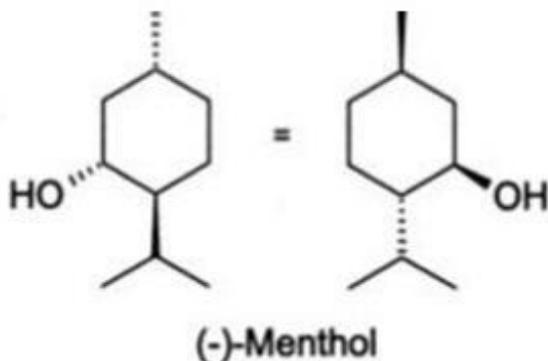
Bioaches Patch contains capsaicin and menthol in a localized dermal delivery system. The capsaicin in Bioaches Patch is a synthetic equivalent of the naturally occurring compound found in chili peppers. Capsaicin is soluble in alcohol, acetone, and ethyl acetate and very slightly soluble in water. The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

Bioaches Patch is a single-use patch stored in a foil pouch. Each Bioaches Patch is 7.6 cm x 12.7 cm (97 cm²) and consists of a polyester backing film coated with a drug-containing silicone adhesive mixture, 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) and it has the following structure:



The empirical formula for menthol is C₁₀H₁₈O, 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). It has the following structure:



Each Bioaches Patch contains 0.0375% capsaicin (0.0375 grams of capsaicin per patch) and 5.00% menthol (5 grams of menthol per patch).

INDICATIONS AND USAGE

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

Bioaches Patch is an external analgesic/counterirritant.

CONTRAINDICATIONS

Bioaches Patch is contraindicated 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 conditions worsen, 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

Bioaches patch contains 0.0375% capsaicin and 5.00% menthol

Instructions for Use

Clean and dry affected area

Tear open pouch. Unseal bag and remove patch

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	<ul style="list-style-type: none">• apply to affected area• change patch 1 to 2 times daily
Children under 12 years	<ul style="list-style-type: none">• consult physician before use

Inactive Components: Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Diazolidinyl Urea, EDTA Disodium Salt, Glycerin, Iodopropynyl Butyl carbamate, Methylparaben, Polysorbate 80, Propylparaben. Sodium Polyacrylate and Water.

HOW SUPPLIED

Bioaches patch is supplied as

Box of 15 patches: 3 pouches each containing 5 patches

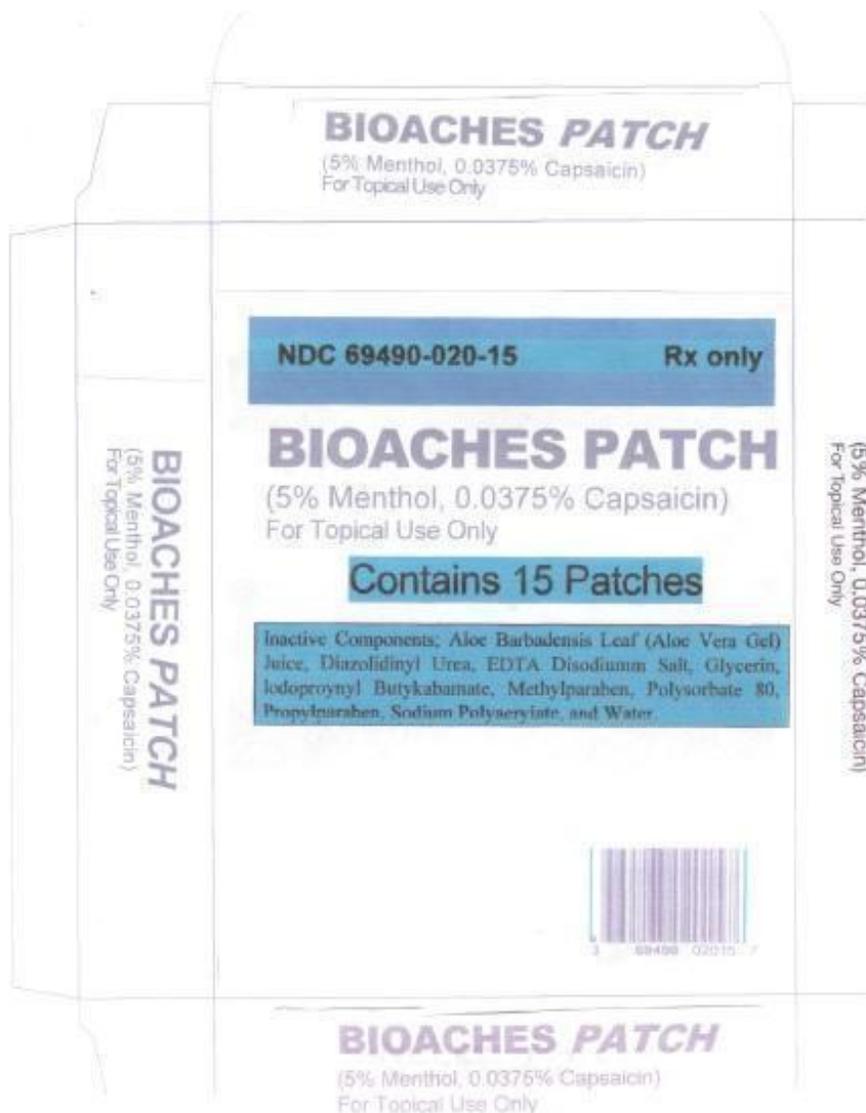
Box of 1 patch: 1 Pouch in one Box

Box of 30 patches: 6 pouches each containing 5 patches.

Storage: Store below 25°C. Avoid direct sunlight.

Rx only

Packaging



BIOACHES

capsaicin , menthol patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69490-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)		CAPSAICIN	0.0375 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	5 g	
Inactive Ingredients				
Ingredient Name		Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
GLYCERIN (UNII: PDC6A3C0OX)				
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69490-020-15	3 in 1 BOX		
1		5 in 1 POUCH		
2	NDC:69490-020-01	1 in 1 BOX		
2		1 in 1 POUCH		
3	NDC:69490-020-30	6 in 1 BOX		
3		5 in 1 POUCH		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		01/10/2015		

Labeler - BIO-SANTEE CHEM (014672538)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Bangli Medical Products Co., Ltd		421295875	manufacture(69490-020)

