

PAIN RELIEF PATCH- menthol,capsaicin,menthyl salicylate patch
Hangzhou Jujiu Science & Biotechnology Co.,Ltd.

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.

cold& hot patch

Active Ingredient

Menthyl salicylate 5.00%

Menthol 5.00%

Capsaicin 0.025%

Purpose

Topical analgesic

Use

- Arthritis
- simple backache
- strains
- sprains
- bursitis
- tendonitis
- bruises
- cramps

Warning

Do not apply wounds or damaged skin.

Do not bandage this product or cover with anything other than light clothing

Avoid contact with eyes or mucous membranes.

Ask a doctor or pharmacist before use if you are

- allergic to salicylates
- taking anticoagulant medications .

When using this product

- For external use only, to relieve the temporary pain.

The application of external heat, such as a heating pad may result in excessive skin irritation or skin burn.

Stop use and ask a doctor if

- rash, irritation, excessive redness, burning or discomfort of the skin develop.
- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product with any other heating or cooling device or with other external analgesic products.

Keep out of reach of children, Children 12 years of age and under should only use this product upon the advice of a healthcare practitioner.

Directions

- Adults: Apply Pain relief patch to the affected area not more than 3 to 4 times daily.
- For children under 12 years of age, consult your health care practitioner.
- Open pouch and remove patch.
- If desired, cut patch to size.
- Peel off protective film and apply sticky side to desired area.
- Remove patch before applying a new one.
- Dispose of patch in waste receptacle.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a healthcare practitioner.

Inactive Ingredients

Aluminium glycinates, Ethylene Diamine Tetraacetic Acid, Polysorbate 80, Titanium dioxide, Purified water, Tartaric acid, Glycerin, Sodium polyacrylate, Carbomer, Sodium carboxymethyl cellulose



PAIN RELIEF PATCH

menthol,capsaicin,menthyl salicylate patch

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69963-001

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	
	MENTHYL SALICYLATE, (+/-)- (UNII: 43XOA705ZD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MENTHYL SALICYLATE, (+/-)-	5 g in 100 g	
	CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	ALUMINIUM TRIGLYCINATE (UNII: 5TLG1CL557)	0.025 g in 100 g		
	DIAMINO HYDROXYPRO PANETETRAACETIC ACID (UNII: 949B9ZMO7M)	0.025 g in 100 g		
	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.025 g in 100 g		
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	0.025 g in 100 g		
	WATER (UNII: 059QF0K00R)	0.025 g in 100 g		
	TARTARIC ACID (UNII: W4888119H)	0.025 g in 100 g		
	GLYCERIN (UNII: PDC6A3C0OX)	0.025 g in 100 g		
	SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	0.025 g in 100 g		
	CARBOMER 940 (UNII: 4Q93RCW27E)	0.025 g in 100 g		
	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	0.025 g in 100 g		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69963-001-01	5 in 1 POUCH	01/08/2018	
1		0.5 g in 1 KIT; 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	07/10/2015	

Labeler - Hangzhou Jujiu Science & Biotechnology Co.,Ltd. (543207110)

Registrant - Hangzhou Jujiu Science & Biotechnology Co.,Ltd. (543207110)

Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Jujiu Science & Biotechnology Co.,Ltd.		543207110	manufacture(69963-001)