

SINSINPAS AREX FLEX GEL PAIN RELIEVING PATCH- l-menthol patch
Sinsin Pharmaceutical Co., Ltd.

Active Ingredients

L-Menthol 76.8mg

Methyl Salicylate 57.6mg

DL-Camphor 96.0mg

Purpose

Topical Analgesic

For the temporary relief of minor aches and pains of muscles and joints associated with:

- Arthritis
- Simple backache
- Strains
- Bruises
- Sprains

For external use only

Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

Do not use

- on wounds or damaged skin
- if you are allergic to any ingredients of this product
- with a heating pad

When using this product

- use only as directed
- avoid contact with eyes, mucous membranes, and rashes

Stop use and ask a doctor if

- skin reactions such as redness, itching, rash, excessive irritation, burning sensation, swelling or blistering occur
- condition worsens
- symptoms persist for longer than 7 days
- symptoms clear up and reoccur within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children.

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

Directions

Adults and children 12 years of age and over:

- clean and dry affected area
- remove patch from film
- apply to affected area not more than 3 times daily
- remove patch from skin after at most 8 hours of application

children under 12 years of age: Consult a doctor

Other Information

- avoid storing product in direct sunlight
- protect product from excessive moisture

Inactive Ingredients

Butylated hydroxytoluene, Methylparaben, Polysorbate 80, Castor Oil, D-Sorbitol Solution,

Concentrated Glycerin, Dihydroxyaluminum, Aminoacetate, Disodium Edetate Hydrate, Carboxymethylcellulose sodium, Kaolin, Titanium Dioxide, Sodium Polyacrylate, Aloe Vera Gel, Gelatin, Nikasol TS-620, Tartaric Acid, Nonylic acid vanillyamide, Purified Water



SINSINPAS AREX FLEX GEL PAIN RELIEVING PATCH

l-menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55264-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	57.6 mg
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	96 mg
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	76.8 mg

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TARTARIC ACID (UNII: W4888I119H)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SORBITOL (UNII: 506T60A25R)	
GELATIN (UNII: 2G86QN327L)	
CASTOR OIL (UNII: D5340Y2I9G)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
NONIVAMIDE (UNII: S846B891OR)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
KAOLIN (UNII: 24H4NWX5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-116-02	1 in 1 POUCH	05/01/2024	
1	NDC:55264-116-01	6 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 Drug	M017	05/01/2024	

Labeler - Sinsin Pharmaceutical Co., Ltd. (823149161)

Registrant - Sinsin Pharmaceutical Co., Ltd. (687867143)

Establishment

Name	Address	ID/FEI	Business Operations
Sinsin Pharmaceutical Co., Ltd.		687867143	manufacture(55264-116)

Revised: 5/2024

Sinsin Pharmaceutical Co., Ltd.