SINSINPAS AREXGEL- I-menthol patch Sinsin Pharmaceutical Co., Ltd.

SINSINPAS AREX GEL PATCH

Active Ingredients

L-Menthol 76.8mg Methyl Salicylate 57.6mg DL-Camphor 96.0mg

Purpose

Topical Analgesic

Uses

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

- Arthritis
- Simple backache
- Strains
- Bruises
- Sprains

Warnings

For external use only

Do not use

- on wounds or damaged skin
- if you are allergic to any ingredients of this product
- with a heating pad
- with, or at the same time as, other external analgesic products

Ask a doctor before use if you are allergic to any ingredients in this product.

When using this product

- do not use other than directed
- avoid contact with eyes, mucous membranes, and rashes

Stop use and ask a doctor if

- rash, itching, or excessive skin irritation develops
- 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.

Caution: This product contains natural rubber latex which may cause allergic reactions.

Keep out of reach of children

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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 no more than 3 to 4 times daily for 7 days
- Remove patch from skin after at most 8 hours' application

Children undress 12 years of age: consult a doctor

Other Information

- Avoid storing product in direct sunlight
- Protect from excessive moisture

Inactive Ingredients

Aloe vera gel, Butylated hydroxytoluene, Carboxymethylcellulose sodium, Castor oil, Concentrated glycerin, Disodium edetate hydrate, Dihydroxyalumium Aminoacetate, Gelatin, Kaolin, Methylparaben, Nonivamide, Polysorbate 80, Purified water, Sodium polyacrylate, Sorbitol, Tartaric acid, Titanium dioxide

SINSINPAS AREX GEL PATCH





SINSINPAS AREXGEL

I-menthol patch

Product	Information	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55264-114

Route of Administration TOPICAL

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

Inactive Ingredients	
Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
NONIVAMIDE (UNII: S846B891OR)	
SORBITOL (UNII: 506T60A25R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
KAOLIN (UNII: 24H4NWX5CO)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CASTOR OIL (UNII: D5340Y2I9G)	
WATER (UNII: 059QF0KO0R)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-114- 02	1 in 1 POUCH	08/27/2021	
1	NDC:55264-114- 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	08/27/2021	

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(55264-114)		

Revised: 1/2024 Sinsin Pharmaceutical Co., Ltd.