SINSINPAP COOL- levomenthol, thymol, camphor, mentha, eucalyptus patch Sinsin Pharmaceutical 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.

SINSINPAP COOL

Active ingredients

L-Menthol 49.4 mg

Thymol 16.5 mg

DL-Camphor 82.4 mg

Mentha Oil 164.7 mg

Eucalyptus Oil 16.5 mg

Purpose

Topical Analgesic

Uses

Temporarily relieves minor pain associated with

- muscular pain
- joint pain
- backache
- bruise
- sprain

Warnings

For external use only

When using this product:

- use only as directed
- do not bandage tightly or use with a healing pad
- avoid contact with the eyes and mucous membranes
- do not apply to wounds or damaged skin

Stop use and ask a doctor if

- conditions worsens
- symptoms persist for more than 7 days or clear up and occur again within a few

days

- redness is present
- skin irritation develops

Keep out of reach of children.

If swallowed, get medical help from hospital right away

Directions

- Adults and children 12 years of age and over: apply to affected area not more than 3 to 4 times daily.
- Children under 12 years of age: do not use, consult a doctor
- For easy application: partially peel back protective film and apply exposed patch to the site of pain.
- Carefully remove remaining film while pressing patch to skin for secure adhesion.

Storage condition

- avoid storing product in direct sunlight
- store at room temperature

Inactive ingredients

BHT, Castor oil, Concentrated Glycerin, Disodium edetate hydrate, D-sorbitol, Isopropyl myristate, Kaolin, Magnesium aluminometasilicate, Methyl Paraben, PEG-4 stearate, Polysorbate 80, Titanium dioxide, Carboxymethylcellulose Sodium, Sodium Polyacrylate, Polyvinyl alchol, Gelatin, Tataric acid, Purified water

Manufactured by:

SINSIN PHARM. CO., LTD.

Distributed by SS Pharmed USA

Made in Korea

NDC #: 55264-012-01

Principal Display Panel

COLORS 3C(K+W+P)

EUCALYPTUS OIL

16.5 mg

17년 10월 12일 : 미국 수출용 신규

(기존 내수 파우치에 영문스티커를 부착하여 판매 하던 것을 별도에 전용 부자재를 제작하여 수출하려 합니다.)



SINSINPAP COOL

levomenthol, thymol, camphor, mentha, eucalyptus patch

EUCALYPTUS OIL (UNII: 2R040NI662) (EUCALYPTUS OIL - UNII:2R040NI662)

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55264-012 **Route of Administration** TOPICAL, CUTANEOUS, TRANSDERMAL

Active Ingredient/Active Moiety Basis of Ingredient Name Strength Strength **LEVOMENTHOL** (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7) LEVOMENTHOL 49.4 mg THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E) THYMOL 16.5 mg CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) -**CAMPHOR** 82.4 mg UNII:5TJD82A1ET) (SYNTHETIC) PEPPERMINT OIL (UNII: AV092KU4JH) (PEPPERMINT - UNII:V95R5KMY2B) PEPPERMINT OIL 164.7 mg

Inactive Ingredients				
Ingredient Name	Strength			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
CASTOR OIL (UNII: D5340Y2I9G)				
GLYCERIN (UNII: PDC6A3C0OX)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
SORBITOL (UNII: 506T60A25R)				

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
SILODRATE (UNII: 9T3UU8T0QK)	
METHYLPARABEN (UNII: A218C7H19T)	
PEG-4 STEARATE (UNII: J33E8608YN)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
TARTARIC ACID (UNII: W48881119H)	
WATER (UNII: 059QF0KO0R)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55264-012- 05	1 in 1 CARTON	05/30/2016			
1	NDC:55264-012- 04	5 in 1 POUCH; Type 0: Not a Combination Product				

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part348	05/30/2016				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

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(55264-012)			

Revised: 2/2023 Sinsin Pharmaceutical Co., Ltd.