

SINSINPAS COLD- l-menthol patch
Sinsin Pharmaceutical Co., Ltd.

SINSINPAS COLD PATCH

Active Ingredients

L-Menthol (5%)

Purpose

Topical Analgesic

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.

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

When using this product

- do not use otherwise than directed
- avoid contact with eyes, mucous membranes or rashes
- do not bandage tightly

Ask a doctor before use if you are prone to allergic reaction from aspirin or salicylates

Stop use and ask a doctor if

- rash, itching, or excessive skin irritation develops
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

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

Directions

Adults and children 12 years of age and over:

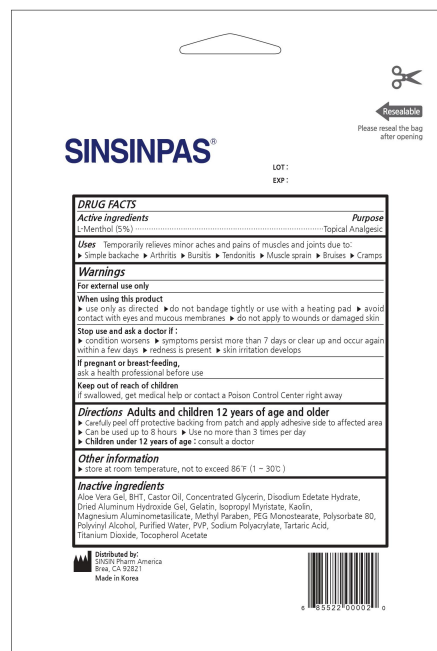
- Clean and dry affected area
- Remove patch from film
- Apply to affected area no more than 3 to 4 times daily for 7 days
- Remove patch from skin after at most 8 hours' application

Children undress 12 years of age: consult a doctor

Inactive Ingredients

Aloe vera gel, BHT, Castor oil, concentrated glycerin, disodium edetate hydrate, dried aluminum hydroxide gel, gelatin, isopropyl myristate, kaolin, magnesium aluminometasilicate, methyl paraben, PEG monostearate, polysorbate 80, polyvinyl alcohol, purified water, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate.

SINSINPAS COLD PATCH



SINSINPAS COLD

l-menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55264-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.85 g in 17 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POVIDONE (UNII: FZ989GH94E)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GELATIN (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TARTARIC ACID (UNII: W4888I119H)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SILODRATE (UNII: 9T3UU8T0QK)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CASTOR OIL (UNII: D5340Y2I9G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-104-02	4 in 1 POUCH	08/01/2018	
1	NDC:55264-104-01	17 g in 1 PATCH; Type 0: Not a Combination Product		

SINSINPAS®



Resealable

Please reseal the bag after opening

 Do Not Reuse

DRUG FACTS

Active ingredients L-Menthol 5%Topical Analgesic

Uses Temporarily relieves minor aches and pains of muscles and joints due to:

▶ Simple backache ▶ Arthritis ▶ Bursitis ▶ Tendinitis ▶ Muscle sprain ▶ Bruises ▶ Cramps

Warnings

For external use only

When using this product

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

Stop use and ask a doctor if :

▶ condition worsens ▶ symptoms persist more than 7 days or clear up and occur again within a few days ▶ redness is present ▶ skin irritation develops

If pregnant or breast-feeding,

ask a health professional before use

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 older

▶ Carefully peel off protective backing from patch and apply adhesive side to affected area
▶ Can be used up to 8 hours ▶ Use no more than 3 times per day
▶ Children under 12 years of age : consult a doctor


Other information

▶ store at room temperature, not to exceed 86°F (1 ~ 30°C)

Inactive ingredients

Aloe Vera Gel, BHT, Castor Oil, Concentrated Glycerin, Disodium Edetate Hydrate, Dried Aluminum Hydroxide Gel, Gelatin, Isopropyl Myristate, Kaolin, Magnesium Aluminummetasilicate, Methyl Paraben, PEG Monostearate, Polysorbate 80, Polyvinyl Alcohol, Purified Water, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Tocopherol Acetate

us80000 / CN180510

 Distributed by:
SINSIN Pharm America
Brea, CA 92821
Made in Korea

LOT :
EXP :



8mm

4mm

8mm

3mm

8mm

3mm



Resealable

Please reseal the bag after opening

SINSINPAS[®]

Pain Relieving

COLD PATCH

COLD Therapy

Cooling Menthol Effect

Muscle & Joint Relief

2 PATCHES
3 1/8 IN X 4 5/8 IN (8 cm X 12 cm) EACH

***Efecto
refrescante!***

8mm

8mm

8mm

8mm

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/01/2018	

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(55264-104)