

AREX SINSIN PAS- camphor, mentha oil, menthol, methyl salicylate, zinc oxide 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.

Arex Sinsin Pas Large

Active ingredients

DL-Camphor 34.10mg

L-Menthol 90.90mg

Mentha Oil 45.46mg

Methyl Salicylate 90.90mg

Zinc Oxide 431.82mg

Purpose

Topical Analgesic

Uses

For temporary 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 aspirin or salicylates
- 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 of this product

When using this product

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

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

Keep out of reach of children.

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

Caution:

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

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 to 4 times daily for 7 days.
- Remove patch from skin after at most 8 hours application.

Children under 12 years of age:

- Consult a doctor.

Other information

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

Inactive ingredients

Benzyl Nicotinamide, Butylated Hydroxytoluene, Calcium Carbonate, Glyceril Rosinate, Natural Rubber, Polyisobutylene, Polybutene, Quintone, Vanillyl Nonylamide, YS Resin.

FDA NDC No.: 55264-021-06

Distributed by:

SINSIN PHARM AMERICA

Brea, CA 92821

www.sinsinpas.us

Principal Display Panel

PRODUCT NAME	usa0129 아렉스 대형 6매	SIZE	전폭 444mm / 아이마크 157mm / 파우치완제품사이즈 : 200 x 157mm	COLORS	5C(CMYK+W)
COMMENTS	14.06.02 : [규격] 내수용 아렉스 대형과 동일 / [디자인] 리뉴얼 / [법적표시기재사항] 18.06.13 : 미국현지 리뉴얼디자인을 채택해 자사 설비로는 불량률이 높은 디자인이라 수정, 영문이이른 전면 적용, CN갱신 19.10.11 : 바코드변경, 사용중지 내용 추가, CN갱신				

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AREX SINSIN PAS

camphor, mentha oil, menthol, methyl salicylate, zinc oxide patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55264-021
Route of Administration	TOPICAL, CUTANEOUS, TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPBOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPBOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPBOR (SYNTHETIC)	34.1 mg
PEPPERMINT OIL (UNII: AV092KU4JH) (PEPPERMINT - UNII:V95R5KMY2B)	PEPPERMINT OIL	45.46 mg
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	90.9 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	90.9 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	431.82 mg

Inactive Ingredients

Ingredient Name	Strength
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BENZYL NICOTINAMIDE (UNII: HF1W0213QP)

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)

CALCIUM CARBONATE (UNII: H0G9379FGK)

GLYCERIN (UNII: PDC6A3COOX)

ROSIN (UNII: 88S87KL877)

NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)

POLYISOBUTYLENE (200000 MW) (UNII: Z6Y02I0591)

POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)

NONIVAMIDE (UNII: S846B891OR)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-021-06	1 in 1 CARTON	11/09/2018	
1		6 in 1 POUCH; Type 0: Not a Combination Product		

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part348	07/26/2013	
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Labeler - Sinsin Pharmaceutical Co., Ltd. (823149161)

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

Establishment

Name	Address	ID/FEI	Business Operations
Sinsin Pharmaceutical Co., Ltd.		687867143	manufacture(55264-021)

Revised: 2/2023

Sinsin Pharmaceutical Co., Ltd.