

**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.*

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**Arex Sinsin Medium**

**Active ingredients**

DL-Camphor 17.05mg

L-Menthol 45.45mg

Mentha Oil 22.73mg

Methyl Salicylate 45.45mg

Zinc Oxide 215.91mg

**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.

**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, Glyceryl Rosinate, Natural Rubber, Polyisobutylene, Polybutene, Quintone, Vanillyl Nonylamide, YS Resin.

FDA NDC No.: 55264-020-10

**Manufactured by:**

**SINSIN PHARM. CO., LTD.**

90, Beomjigi-ro 141 beon-gil, Danwon-gu, Ansan-si, Gyeonggi-do, Korea

tel: 82-31-776-1140~3 <http://www.sinsin.com>

# Principal Display Panel

PRODUCT NAME	usa0130 아렉스 중형 10매	SIZE	전폭 424mm / 아이마크 132mm / 파우치완제품사이즈 : 190 x 132mm	COLORS	5C(CMYK+W)
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COMMENTS 18.06.13 : 미국 현지 리뉴얼 디자인을 채택해 차사 설비로는 불량률이 높은 디자인이라 수정, 영문아이콘 전면 적용, CN갱신  
19.10.11 : 바코드변경, 사용중지 내용 추가, CN갱신

C M Y K  WHITE



## AREX SINSIN PAS

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

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55264-020
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)	17.05 mg
PEPPERMINT OIL (UNII: AV092KU4JH) (PEPPERMINT - UNII:V95R5KMY2B)	PEPPERMINT OIL	22.73 mg
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	45.45 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	45.45 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	215.91 mg

### Inactive Ingredients

Ingredient Name	Strength
BENZYL NICOTINAMIDE (UNII: HF1W0213QP)	

**BUTYLATED HYDROXYTOLUENE** (UNII: 1P9D0Z171K)

**CALCIUM CARBONATE** (UNII: H0G9379FGK)

**GLYCERIN** (UNII: PDC6A3C0OX)

**ROSIN** (UNII: 88S87KL877)

**NATURAL LATEX RUBBER** (UNII: 2LQ0UUW8IN)

**POLYISOBUTYLENE (200000 MW)** (UNII: Z6Y02I0591)

**POLYBUTENE (1400 MW)** (UNII: 1NA5AO9GH7)

**NONIVAMIDE** (UNII: S846B891OR)

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-020-10	1 in 1 CARTON	11/09/2018	
1		10 in 1 POUCH; Type 0: Not a Combination Product		

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**C M Y K**  WHITE



### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part348	08/31/2015	
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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(55264-020)

Revised: 2/2023

Sinsin Pharmaceutical Co., Ltd.