#### 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 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 Nicothinamide, Butylated Hydroxytoluene, Calcium Carbonate, Glyceryl 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**



#### **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 Basis of Ingredient Name** Strength Strength CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) -CAMPHOR 34.1 mg UNII:5TJD82A1ET) (SYNTHETIC) **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:0414PZ4LPZ) METHYL SALICYLATE 90.9 mg **ZINC OXIDE** (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 431.82 mg

**Inactive Ingredients** 

**Ingredient Name** 

Strength

BENZYL NICOTIN	IAMIDE (UNII: HF1W0213QP)						
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)							
CALCIUM CARBONATE (UNII: H0G9379FGK)							
GLYCERIN (UNII: PDC6A3C0OX)							
ROSIN (UNII: 88587KL877)							
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 Star Date		Marketing End Date		
<b>1</b> NDC:55264-021	1 in 1 CARTON		11/09/2018				
1	6 in 1 POUCH; Type 0: Not a Combination Product						
PRODUCT NAME USa0129	아렉스 대형 6매 sıze 전폭 444mm / 아이		베포사이즈 : 200 x 157mm	COLORS 5C(CMYK+)	 //)		
COMMENTS         14.06.02 : [규격] 내수용 아렉스 대형과 동일 / [디자인] 리뉴얼 / [법적표시기재사항]           18.06.13 : 미국현지 리뉴얼디자인을 재배치 자사 설비로는 불량률이 높은 디자인이라 수정, 영문아이콘 전면 적용, CN갱신							
19.10.11 : 바코드변경, 사용중지 내용 추가, CN갱신							
C M Y K 🗌 WHITE							
-		4. 비행 문논홈위치 (Malania) 프			L suos L		
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		<b>% ¥</b> ₽					
SI	DSINPAS <sup>°</sup>	d uado and		COOL			
		and Cut c	A	REH Hot			
		Rese	Active ingredients Purpose	use and ask a doctor if b), liching, or excessive skin initation develops indition workens mptome presist for longer than 7 days			
	INSTANT PAIN RELIEF		L-Menthel 90.90mg Topical Analgesic Providence Company Topical Analgesic Providence Company Topical Analgesic Providence Company Topical Analgesic Revenues	mptons clear up and reoccur within a few days. sgnant or breast-feeding, sik a health professional before use o out of reach of children. Blowed, get medical help or contact a Poison Control Center right aways			
			Uses For temporary relief of minor aches and pains of muscles and joints associated with: # Arthritis # Simple backache # Strains # Bruises # Sprains Dire	tion: This product contains natural rubber latex which may cause gic reactions.	21mm		
	- JOINT PAIN - MUSCLE PAIN		Warnings         Adu           For extremal use only         CR           Do not use         PR           = Cn vecurds or damaged skin         FR	Its and children 12 years of age and over an and dry affected area      Remove patch from film pip to affected area no more than 3 to 4 time ship for 7 days move patch from skin after at most 8 hours of application lidene under 12 years of age Consist a doctor			
	- MOSCLE FAINS - SPRAINS - BACKACHE		With a heating pad     With a heating pa	her information aid staring product in direct sunlight Protect from excessive moistus ctive ingredients			
	Cool & Hot Pain Relieving Patch		When using this product Beru a Do not use other than directed Glyco a Avoid contact with eyes, mucous membranes, and rashes Vari	yl Nicotinate, Butylated Hydroxytoluene, Calcium Carbonate, eryl Rosinate, Natural Rubber, Polyisobutylene, Polybutene, Quintone, Iyl Norylamide, YS Resin.			
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Marketing Information							
Marketing	Application Number of	r Monogrant	Marketing St	tart Mark	eting End		
Category	Citation		Date		Date		

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07/26/2013

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

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

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

Revised: 2/2023

Sinsin Pharmaceutical Co., Ltd.