SINSINPAS AREXLOTION- I-menthol lotion Sinsin Pharmaceutical Co., Ltd.

SINSINPAS AREX LOTION

Active Ingredients

Methyl Salicylate 200.0mg L-Menthol 60.0mg

Tocopherol Acetate 1.0mg

Purpose

Topical Analgesic

Uses

Temporarily relieves minor pain associated with:

- Arthritis
- Simple backache
- Muscle strains
- Sprains
- Bruises
- Cramps

Warnings

For external use only

allergy alert: If prone to allergic reaction from aspirin or salicylates or allergic to any ingredients in this product, consult a doctor before use.

When using this product

- use only as directed
- avoid contact with eyes and mucous membranes or rashes
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken irritated skin
- do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use
- do not use at the same time as other topical analgesics
- a transient burning sensation may occur upon application but generally disappears in several days
- if severe burning sensation occurs, discontinue use immediately
- do not expose the area treated with product to heat or direct sunlight
- avoid applying into skin folds

stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

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.

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.

Directions

Adults and children 12 years of age and over:

- apply a thin layer to affected area
- massage into painful area until thoroughly absorbed into skin

repeat as necessary, but no more than 3 to 4 times daily

• AFTER APPLYING, WASH HANDS WITH SOAP AND WATER

Children undress 12 years of age: ask a doctor

Other Information

- Avoid storing product in direct sunlight, store at 20-25C (68-77F)
- Store with lid closed tightly

Inactive Ingredients

Nonylic acid vanillyamide, Carbomer 941, Light liquid paraffin, Polysorbate 60, Sorbital Monostearate. Lanolin oil, Triethanolamine, Fresh yuja flavor, Purified water

SINSINPAS AREX LOTION





Drug Facts

Active ingredients	Purpose	
Methyl Salicylate 200.0mg	Topical analgesic	
L-Menthol 60.0mg	Topical analgesic	
Tocopherol Acetate 1.0mg	Topical analgesic	

Uses temporarily relieves minor pain associated with: *arthritis *simple backache *muscle strains *sprains *bruises *cramps

Warnings For external use only

Allergy alert: If prone to allergic reaction from aspirin or salicylates or allergic to any ingredients in this product, consult a doctor before use.

When using this product - we will deduce the second of the

Stop use and ask a doctor if "condition viceses where is present window deelings symptoms greated more than 7 days or dear up and coor again within a leverable "you experience signs of with righty, such as pair, weeking, or bits reing where the product was applied.

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

Frequency of reach of children. Fudios de mediant protessorian between the Directions

Adults and children 12 years of age and over-upy a hinge to dictid are managenth parties are off township shooted displan regard account of the total children 12 years of age and over-upy a bid from the parties are managenth parties are off township shooted displan regard account but not one that 16 time daily **AFTER APPLYING, WASH HANDS WITH SOAP AND WATER distinct layers or younge to skill obdoor.

Other information

Avoid storing product in direct smilight, store at 20-25°C(68-77°F) Store with lid closed tightly

Inactive ingredients

Inactive ingredients

Inactive ingredients

Norylic acid vanilyamide, Carbomer 941, Light liquid paraffin, Polysorbate 60, Sorbitan Monostearate, Lanolin Oil, Triethanolamine, Fresh yuja flavor, Purified Water



Distributed by: SINSIN PHARM AMERICA Brea, CA 92821



Drug Facts

Active ingredients Purpose Methyl Salicylate 200.0mg. .Topical analgesic L-Menthol 60.0mg..... Tocopherol Acetate 1.0mg.... .Topical analgesic .. Topical analgesic

Uses

temporarily relieves minor pain associated with:

*arthritis *simple backache *muscle strains *sprains *bruises *cramps

Warnings For external use only

Allergy alert: If prone to allergic reaction from aspirin or salicylates or allergic to any ingredients in this product, consult a doctor before use.

When using this product

· use only as directed. • avoid contact with eyes and mucous membranes or rashes • rare cases of serious burns have been reported with products of this type • do not apply to wounds or damaged, broken irritated skin • do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use • do not use at the same time as other topical analgesics • a transient burning sensation may occur upon application but generally disappears in several days • if severe burning sensation occurs, discontinue use immediately • do not expose the area treated with product to heat or direct sunlight • avoid applying into skin folds

Stop use and ask a doctor if

 condition worsens * redness is present * irritation develops * symptoms persist for more than 7 days or dear up and occur again within a few days • you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

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 over:

apply a thin layer to affected area
 massage into painful area until thoroughly absorbed into skin
 repeat as necessary, but no more than 3 to 4 times daily

• AFTER APPLYING, WASH HANDS WITH SOAP AND WATER

children 12 years or younger: ask a doctor

Other information

Avoid storing product in direct sunlight, store at 20-25 °C(68-77 °F) Store with lid closed tightly

Inactive ingredients

Nonylic acid vanillyamide, Carbomer 941, Light liquid paraffin, Polysorbate 60, Sorbitan Monostearate, Lanolin Oil, Triethanolamine, Fresh yuja flavor, Purified Water





MAXIMUM STRENGTH

SPRAINS



Distributed by: SINSIN PHARM AMERICA Brea, CA 92821 www.sinsinpas.us

LOT:

EXP:

SINSINPAS AREXLOTION

I-menthol lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55264-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	200 mg	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (ALPHA-TOCOPHEROL - UNII: H4N855PNZ 1)	ALPHA-TOCOPHEROL ACETATE	1 mg	
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	60 mg	

Inactive Ingredients			
Ingredient Name	Strength		
POLYSORBATE 60 (UNII: CAL22UVI4M)			
LANOLIN OIL (UNII: OVV5IIJ58F)			
SORBITAN MONOSTEARATE (UNII: NVZ 4I0H58X)			
TROLAMINE (UNII: 903K93S3TK)			
CITRUS JUNOS FRUIT (UNII: 53KHW58C1V)			
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
NONIVAMIDE (UNII: S846B891OR)			
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-112- 02	1 in 1 BOX	08/27/2021	
1	NDC:55264-112- 01	1 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	08/27/2021		

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(55264-112)	

Revised: 1/2024 Sinsin Pharmaceutical Co., Ltd.