

SINSIN MULPAS- l-menthol, methyl salicylate, dl-camphor, chlorpheniramine maleate, thymol liquid

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.

SINSIN MULPAS

Active Ingredients

L-menthol

Methyl salicylate

dl-camphor

Chlorpheniramine maleate

Thymol

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 2 years of age and over:

- Apply to affected area no more than 3 to 4 times daily
- Children under 12 years of age: consult a doctor

Inactive Ingredients

concentrated glycerin, ethanol, purified water, vanillyl nonylamide.

SINSIN Mulpas

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55264-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4500 mg in 120 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	6900 mg in 120 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	100 mg in 120 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4200 mg in 120 mL

Inactive Ingredients

Ingredient Name	Strength
NONIVAMIDE (UNII: S846B891OR)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-107-02	1 in 1 BOX	02/12/2019	
1	NDC:55264-107-01	120 mL in 1 CONTAINER; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/01/2019	

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(55264-107)

Revised: 12/2019

Sinsin Pharmaceutical Co., Ltd.