# CRAMERGESIC- menthol, methyl salicylate ointment Performance Health, LLC

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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## **Cramergesic Ointment**

# **Drug Facts**

## **Active Ingredients**

Menthol 1.9%

Methyl Salicylate 13.7%

# **Purpose**

Counterirritant

#### Uses

For the temporary relief of minor aches and pains of muscles and joints associated with strains, sprains, bruises, simple backache, and arthritis. Combined with stretching and calisthenics, Cramergesic assists in the warm-up process, especially in cool, damp weather. Do not bandage tightly.

# **Warnings**

# For external use only.

Use only as directed. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Do not apply to wounds or damaged skin. Avoid contact with the eyes. If condition worsens, or if the symptoms persist for more than 7 days, or clear up and occur again within a few days, discontinue use and consult a doctor. Consult a doctor before administering to children, including teenagers, with chicken pox or flu.

# Keep this and all drugs out of the reach of children

to avoid accidental poisoning.

#### **Directions**

Gently massage into painful area. Adults and children 6 years of age and older: apply to affected area not more than 3 - 4 times daily. Children under 6 years of age: consult a doctor. To apply Cramergesic pack: spread 1/8 " layer of Cramergesic over area. Do not bandage tightly.

#### Other information

Discontinue use if excessive irritation of skin develops. Use with caution on fair skin. Store in a cool, dry place with cap closed tightly.

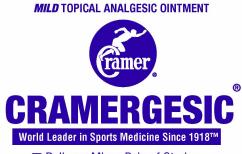
# **Inactive Ingredients**

Lanolin, Paraffin, Petrolatum

## **Questions?**

(800) 345-2231

# **Package Labeling:**



- Relieves Minor Pain of Strains and Sprains
- Relaxes Tight, Aching Muscles
- Assists in Warm-up

NET WT 5 Lb (2.268 kg)



CRAMERGESIC ANALGESIC OINTMENT MILD

Drug Facts

Active Ingredients	Purpose	
Menthol 1.9%	Counterirritant	
Methyl Salicylate 13.7%	Counterirritant	
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Other Information		
Discontinue use is excessive irritation of skin develops. Use with caution on sensitive skin. Store in a cool, dry place with cap closed tightly.		
Inactive Ingredients		
Lanolin, Paraffin, Petrolatum		
Questions? (800) 345-2231	Made in the U.S.A.	
Stock No. 034540 P08497 Rev 2	NDC 59316-998-97	
Performance Health, LLC. Akron, Ohio 44310		

## **CRAMERGESIC**

menthol, methyl salicylate ointment

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59316-998

**Route of Administration** TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.9 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ 4LPZ)	METHYL SALICYLATE	13.7 g in 100 g

# **Inactive Ingredients**

Ingredient Name	Strength
PARAFFIN (UNII: 1900E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:59316-998- 96	454 g in 1 JAR; Type 0: Not a Combination Product	05/19/2017	12/31/2024	
	2	NDC:59316-998- 97	2268 g in 1 JAR; Type 0: Not a Combination Product	05/19/2017	12/31/2024	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	05/19/2017	12/31/2024		

# Labeler - Performance Health, LLC (794324061)

Revised: 8/2022 Performance Health, LLC