

**COMFORTE NATURAL MENSTRUAL CRAMP RELIEF CREAM- menthol, methyl salicylate cream**  
**PMS4PMS, 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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**comforte Natural Menstrual Cramp Relief Cream**

**Active Ingredient Purpose**

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Menthol 1.4%..... Topical Analgesic

Methyl Salicylate 10% ..... Topical Analgesic

**Purpose**

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Topical Analgesic

**Uses**

**Uses** Temporarily relieves minor pain associated with cramps

**Warnings**

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**For external use only**

**Allergy alert:** if prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

**Stop use and ask a doctor if** \* condition worsens or symptoms persist for more than 7 days \* symptoms clear up and occur again within a few days \* excessive skin irritation occurs

**When using this product** \* use only as directed \* do not bandage tightly or use with a heating pad \* avoid contact with eyes or mucuous membranes \* do not apply to wounds or damaged skin

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

**Keep out of reach of children.** In case of accidental ingestion, get medical help or contact a Poison Control Center right away

**Directions**

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**adults and children over 12 years:** \* apply generously to affected area \* massage into painful area until thoroughly absorbed into skin \* repeat as necessary, but no more than 4 times daily \* **children 12 years or younger;** ask a doctor

**Inactive ingredients** Calotropis Procera Extract, Carapa Procera Oil, Sandalwood Oil, Shea Butter, Soybean Oil

**Questions?** Call 877.590.6257

NDC 73603-141-96. 28 g Tube.



NDC 73603-141-96. Outer carton for 28 g Tube..



COMFORTE NATURAL MENSTRUAL CRAMP RELIEF CREAM

menthol, methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73603-141
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)		METHYL SALICYLATE	10 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	1.4 g in 100 g

Inactive Ingredients				
Ingredient Name				Strength
CARAPA PRO CERA WHOLE (UNII: I9HWQ4A9EV)				
SANDALWOOD OIL (UNII: X7X01WMQ5F)				
CALOTROPIS PRO CERA WHOLE (UNII: M7MHW69IJ8)				
SHEA BUTTER (UNII: K49155WL9Y)				
SOYBEAN OIL (UNII: 241ATL177A)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73603-141-96	1 in 1 CARTON	05/06/2020	
1		28 g in 1 TUBE; 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	05/06/2020	

**Labeler** - PMS4PMS, LLC (117393964)

Establishment			
Name	Address	ID/FEI	Business Operations
PMS4PMS, LLC		117393964	manufacture(73603-141)