

PROHEMP SOOTHING MENTHOL RUB 4%- menthol cream
NATURE'S FUSIONS, 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.

ProHEMP Pain Relief Soothing Menthol Rub 4%

temporarily relieves minor aches and pains of muscles and joints due to • arthritis • simple backache • strains • tendonitis • bursitis • sprains • bruises • cramps

Menthol 4% - External Analgesic

Keep out of reach of children. • If swallowed, get medical help or contact a Poison Control Center right away.

Adults and children 12 or older: apply to affected area as needed, no more than 4 times daily. Children under 12 years: ask a doctor.

aloe vera, beta caryophyllene, cellulose, hemp extract, hyaluronic acid, natural fragrances (essential oils, terpenes), organic fractionated coconut oil, potassium citrate, potassium sorbate, purified water, quillaja saponaria extract

Adults and children 12 or older: apply to affected area as needed, no more than 4 times daily. Children under 12 years: ask a doctor.

For external use only

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not apply to wounds or to damaged or very sensitive skin
- do not bandage tightly or use with a heating pad
- Stop use and ask a doctor if
- excessive redness or irritation is present
- condition worsens
- pain persists for more than 7 days
- symptoms clear up and occur again within a few days
- If pregnant or breastfeeding, 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.



Drug Facts

Active ingredient: Menthol 4% **Purpose:** External Analgesic

Uses: Temporarily relieves minor aches and pains of muscles and joints due to • arthritis • simple backache • strains • tendonitis • sunburns • sprains • bruises • cramps

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Directions: Adults and children 12 or older: apply affected area as needed, no more than 4 times daily. Children under 12 years: ask a doctor.

Inactive ingredients: aloe vera, beta-caryophyllene, cellulose, hemp extract, hyaluronic acid, natural fragrances (essential oils, terpenes), organic fractionated coconut oil, potassium citrate, potassium sorbate, purified water, quillaja saponaria extract

Inflused with Nature's Fusion's Fine & low essential oil blend. Apply to affected area for fast-acting and natural relief.



4 oz jar display panel

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73769-100
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	4 g in 60 mL
Inactive Ingredients			
Ingredient Name			Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
.BETA.-CARYOPHYLLENE ALCOHOL (UNII: 9Y5007OH2E)			
POWDERED CELLULOSE (UNII: SMD1X3XO9M)			
HYALURONATE SODIUM (UNII: YSE9PPT4TH)			
QUILLAJA SAPONARIA BARK (UNII: 8N0K3807Z W)			
FRAGRANCE 13576 (UNII: 5EM498GW35)			
POTASSIUM CITRATE (UNII: EE90ONI6FF)			
HEMP (UNII: TD1MUT01Q7)			

CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73769-100-60	60 mL in 1 TUBE; Type 0: Not a Combination Product	01/31/2022	
2	NDC:73769-100-04	113 mL in 1 JAR; Type 0: Not a Combination Product	01/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/31/2022	

Labeler - NATURE'S FUSIONS, LLC (051472644)

Establishment

Name	Address	ID/FEI	Business Operations
NATURE'S FUSIONS, LLC		051472644	manufacture(73769-100)

Revised: 1/2022

NATURE'S FUSIONS, LLC