

MENTHOL- owell naturals pain relief cream cream
Amish Origins 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.

Owell Naturals Pain Relief Cream

Active Ingredient

Menthol 8%

Purpose

Topical Analgesic

Uses:

Arthritis Pain, Sore Joints and Muscles, Sore Throat, Sinus Trouble, Restless Leg Syndrome

Warnings

- For External Use Only, As Directed!
- Avoid contact with eyes or other sensitive areas.
- If prone to allergic reaction from aspirin or salicylate, consult your doctor before using.
- If conditions persist more than seven days, consult your doctor
- If pregnant or breast-feeding, ask a health professional before use.
- Do not bandage tightly or use a heating pad
- May irritate sensitive skin

- Keep ointment out of reach of children

Directions

Adults and children over 12 years:

- Apply freely to affected areas. Rub well
- **Colds:** Apply on chest, back and neck.
- **Head Colds:** Apply around nostrils, on forehead and behind ears. Place small amount in vaporizer for aid.
- **Sore Throat:** Apply liberally on throat and neck for sore throats

Children 12 years or younger.

- Consult your physician.

INACTIVE INGREDIENTS

Water, Carthamus Tinctorius (Hybrid Safflower) Seed Oil, Cetyl PEG/PPG-10/1 Dimethicone, Aloe Barbadosis (Aloe Vera) Leaf Juice, Beeswax, Hydrogenated Castor oil, Caprylyl Glycol, Phenoxyethanol, Eucalyptus Globulus Leaf Oil, Chlorphenesin, Cinnamomum Camphora Bark Oil, Abies Sibirica Needle Oil, Methyl Salicylate, Sodium Chloride

Owell Naturals
AMISH ORIGINS FORMULA
DEEP PENETRATING
Greaseless Pain Relief Cream
ARTHRITIS • SORE MUSCLES
RESTLESS LEGS • ACHING JOINTS
NATURAL INGREDIENTS 7 FL. OZ, 198.45 GR

Distributed By:
Owell Naturals, L.L.C.
Southfields, NY 10975

Drug Facts		Drug Facts (continued)
Active Ingredient Menthol 8%	Purpose Topical Analgesic	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 - topical irritation occurs
Uses: temporarily relieves minor aches and pains associated with - Arthritis Pain- Sore Joints and Muscles- Sore Throat- Sinus Trouble - Restless Leg Syndrome	Warnings For External Use Only. Allergy Alert: If prone to allergic reaction from aspirin or salicylate, consult your doctor before using. Do not use - on wounds or damaged skin - with a heating pad - on a child under 12 years of age with arthritis-like conditions	Keep out of reach of children to avoid accidental ingestion. If swallowed get medical help or contact a Poison Control Center immediately. Directions - use only as directed - adults and children 12 years of age and older apply to the affected area not more than 3 to 4 times daily - children under 12 years of age, ask a doctor
When Using This Product: - Avoid contact with eyes or other sensitive areas - do not bandage tightly	Ask a doctor before use if you have redness over the affected area.	Other Information - store at room temperature
Questions?	Customer Care: 929-505-9252	INACTIVE INGREDIENTS Water, Carthamus Tinctorius (Hybrid Safflower) Seed Oil, Cetyl PEG/PPG-10/1 Dimethicone, Aloe Barbadosis (Aloe Vera) Leaf Juice, Beeswax, Hydrogenated Castor oil, Caprylyl Glycol, Phenoxyethanol, Eucalyptus Globulus Leaf Oil, Chlorphenesin, Cinnamomum Camphora Bark Oil, Abies Sibirica Needle Oil, Methyl Salicylate, Sodium Chloride

X003F20C A5

MENTHOL

owell naturals pain relief cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62212-505
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
SUNFLOWER SEED OIL GLYCERETH-8 ESTERS (UNII: 358X17CAT0)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
PHENOXYETHANOL (UNII: HIE492Z23T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
CINNAMOMUM CAMPHORA WHOLE (UNII: 0B27814T7X)	
ABIES SIBIRICA LEAF OIL (UNII: XRY0V4VZKZ)	

METHYL SALICYLATE (UNII: LAV5U5022Y)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62212-505-01	198.45 g in 1 JAR; Type 0: Not a Combination Product	07/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/17/2023	

Labeler - Amish Origins LLC (079239259)

Revised: 7/2023

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