**OWELL NATURALS PAIN RELIEF CREAM- menthol cream**
**Owell Naturals Brand LLC**

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## Owell Naturals Pain Relief Cream

Menthol 8%

Topical Analgesic

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
Ask a doctor before use if you have redness over the affected area.
When Using This Product ■ avoid contact with eyes or other sensitive areas ■ do not bandage tightly

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
Keep out of reach of children to avoid accidental ingestion. If swal- lowed, 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 affected area
■ children under 12 years of age: ask a doctor

Inactive ingredients Water, Carthamus tinctorius (Hybrid Safflower) Seed Oil, Helianthus annuus (Sunflower) Seed Oil, Cetyl PEG/PPG-10/1 Dimethicone, Aloe barbadensis (Aloe Vera) Leaf Juice, Beeswax, Hydro- genated Castor Oil, Caprylyl Glycol, Phenoxyethanol, Eucalyptus globulus Leaf Oil, Chlorphenesin, Cinnamomum camphora Bark Oil, Abies sibirica Needle Oil, Methyl Salicylate, Sodium Chloride

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.

# OWELL NATURALS PAIN RELIEF CREAM

menthol cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:83570-500 |
| **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 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **SUNFLOWER SEED OIL GLYCERETH-8 ESTERS** (UNII: 358X17CAT0) | |
| **PEG-8 BEESWAX** (UNII: 3C1QUF1TIR) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **ABIES SIBIRICA LEAF OIL** (UNII: XRY0V4VZKZ) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)** (UNII: V2W71V8T0X) | |
| **EUCALYPTUS GLOBULUS LEAF** (UNII: S546YLW6E6) | |
| **CINNAMOMUM CAMPHORA WHOLE** (UNII: 0B27814T7X) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **METHYL SALICYLATE** (UNII: LAV5U5022Y) | |
| **SAFFLOWER OIL** (UNII: 65UEH262IS) | |
| **CHLORPHENESIN** (UNII: I670DAL4SZ) | |
| **HYDROGENATED CASTOR OIL** (UNII: ZF94AP8MEY) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:83570-500-02 | 60 mL in 1 JAR; Type 0: Not a Combination Product | 09/20/2024 | |
| **2** | NDC:83570-500-03 | 103.5 mL in 1 JAR; Type 0: Not a Combination Product | 09/20/2024 | |
| **3** | NDC:83570-500-07 | 207 mL in 1 JAR; Type 0: Not a Combination Product | 09/20/2024 | |
| **4** | NDC:83570-500-14 | 414 mL in 1 JAR; Type 0: Not a Combination Product | 09/20/2024 | |

## Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|---|---|---|---|

| Category | Citation | Date | Date |
|---|---|---|---|
| OTC Monograph Drug | M017 | 09/20/2024 | |

## Labeler - Owell Naturals Brand LLC (122280778)

Revised: 9/2024 Owell Naturals Brand LLC