

SOOTHE AND MOVE PAIN RELIEF CREAM- camphor cream
Simtec 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.

SOOTHE & MOVE PAIN RELIEF CREAM

DRUG FACTS

Active Ingredients

Camphor 3.18%

Purpose

Topical Analgesic

Uses:

Temporarily relieves the minor aches and pains of joints and muscles associated with simple backache, arthritis, strains, bruises, sprains.

Warnings:

For External Use Only

Do not use:

- Other than as directed
- On wounds or damaged skin
- With a heating pad
- If you are allergic to any ingredient in this product
- On a child under 12 with arthritis-like conditions

When using this product:

- Avoid contact with eyes, wounds, mucus membrane, irritated skin.
- Do not bandage tightly.

Stop use and ask a doctor if:

- Condition worsens, if symptoms persist for more than 7 days or clear up and occur again within a few days.
- Skin redness or excessive irritation of the skin develops.

■ If pregnant or breastfeeding, ask a doctor before use.

Keep out of the reach of children:

If swallowed, get medical help or

contact a Poison Control Center
immediately

Directions:

■ Adults and children 12 years of age
and older: apply to affected area not
more than 3 to 4 times daily.

■ Children under 12 years of age:
ask a doctor

Other Information:

Store in a cool dry place 68 - 77 F
(20 - 25 C) Minor separation may
occur. Shake well before using.

Inactive Ingredients:

Acrylamide/Sodium Acryloyldimethyl
Taurate Copolymer, Aloe Barbadensis
Leaf Juice, Arnica Oil, Behentrimonium
Methosulfate, Caprylic/Capric
Triglyceride, Caprylyl Glycol, Cetearyl
Alcohol, Cetyl Alcohol, Cholecalciferol,
Chondroitin Sulfate, Coenzyme
Q 10, Corn Oil, Deionized Water, Emu
Oil, Glucosamine Sulfate, Glycerin,
Green (Camellia Sinensis) Tea Extract,
Isohexadecane, Peppermint Oil*,
Phenoxyethanol, Polysorbate 80, SO
Alcohol, Shark cartilage, Shea Butter,
Sorbic Acid, Tetrahexyldecyl
Ascorbate, Tocopheryl Acetate,
Yucca (Gluca) Root Extract.

*A source of natural menthol.

Questions?

Call 1-855-223-6010

Weekdays between 9am to 5pm CST

PACKAGE LABELING - PRINCIPAL DISPLAY PANEL

**SOOTHE & MOVE
PAIN RELIEF CREAM**

soothing relief that keeps you moving

Doctor Formulated & Recommended

- Fast Acting Topical
- Deep Penetrating
- No Greasy Residue

ALL33

Net Wt. 2.75 Oz

(77.96 g)

Vitamin C, D, E • Botanicals • Antioxidants

Shake before use

Questions?

call 1-855-223-6010

Weekdays between 9am to 5pm CST

Distributed by Simtec, LLC.

Beverly Hills, CA

**SOOTHE
& MOVE**

PAIN RELIEF CREAM

soothing relief that keeps you moving

• Fast Acting Topical
• Deep Penetrating
• No Greasy Residue

ALL33
Net Wt. 2.75 oz
(77.96 g)

Vitamins C,D,E • Botanicals • Antioxidants

▲ PEEL HERE

Shake before use

DRUG FACTS

Active Ingredients	Purpose
Camphor 3.18%	Topical Analgesic

Uses:

Temporarily relieves the minor aches and pains of joints and muscles associated with simple backache, arthritis, strains, bruises, sprains.

Warnings:

For External Use Only

Do not use:

- Other than as directed
- On wounds or damaged skin
- With a heating pad
- If you are allergic to any ingredient in this product
- On a child under 12 with arthritis-like conditions

Made in the USA



See inside label for complete drug facts



DRUG FACTS (continued)

When using this product:

- Avoid contact with eyes, wounds, mucus membranes, irritated skin.
- Do not bandage tightly.

Stop use and ask a doctor if:

- Condition worsens, if symptoms persist for more than 7 days or clear up

DRUG FACTS (continued)

Other Information:

Store in a cool dry place 68 - 77 F (20 - 25 C) Minor separation may occur. Shake well before using.

Inactive Ingredients:

Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer, Aloe Barbadosis Leaf Juice, Arnica Oil, Behentrimonium

persist for more than 7 days or clear up and occur again within a few days.

■ Skin redness or excessive irritation of the skin develops.

■ **If pregnant or breastfeeding, ask a doctor before use.**

Keep out of the reach of children:

If swallowed, get medical help or contact a Poison Control Center immediately

Directions:

■ Adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily.

■ Children under 12 years of age: ask a doctor

um Methosulfate, Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Chondroitin Sulfate, Coenzyme Q 10, Corn Oil, Deionized Water, Emu Oil, Glucosamine Sulfate, Glycerin, Green (Camellia Sinensis) Tea Extract, Isohexadecane, Peppermint Oil*, Phenoxylethanol, Polysorbate 80, SD Alcohol, Shark Cartilage, Shea Butter, Sorbic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Yucca (Gluca) Root Extract.
* A source of natural menthol.

Questions?

Call 1-855-223-6010

Weekdays between 9am to 5pm CST

Distributed by Simtec, LLC.

Beverly Hills, CA

RES

SOOTHE AND MOVE PAIN RELIEF CREAM

camphor cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78805-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.18 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	

UBIDECARENONE (UNII: EJ27X76M46)
CORN OIL (UNII: 8470G57WFM)
WATER (UNII: 059QF0KO0R)
EMU OIL (UNII: 344821WD61)
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)
GLYCERIN (UNII: PDC6A3C0OX)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
ISOHEXADECANE (UNII: 918X1OUF1E)
PEPPERMINT OIL (UNII: AV092KU4JH)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
ALCOHOL (UNII: 3K9958V90M)
SHARK CARTILAGE (UNII: D2YCN1I522)
SHEA BUTTER (UNII: K49155WL9Y)
SORBIC ACID (UNII: X045WJ989B)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
YUCCA GLAUCA ROOT (UNII: 1A15YBH7N1)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78805-005-01	77.96 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/12/2020	

Labeler - Simtec LLC (117251669)

Revised: 11/2021

Simtec LLC