

EXTRA STRENGTH PAIN RELIEF CREAM- menthol cream
Sagely Enterprises Inc.

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.

Extra Strength Pain Relief Cream

Active ingredient

Menthol 10%

Purpose

Menthol 10%.....Topical analgesic

Uses

temporarily relieves the minor aches and pains of muscles and joints associated with:

- strains
- bruises
- simple backache
- arthritis
- sprains

Warnings

For external use only.

Do not use

- on wounds or damaged, broken, or irritated skin
- with a heating pad

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days or 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.

Directions

- Use only as directed
- **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

Inactive ingredients

Water, Propanediol, Cetyl Alcohol, Caprylic/Capric Triglyceride, Stearyl Alcohol, Glycerin, Capryloyl Glycerin/Sebacic Acid Copolymer, Cetearyl Glucoside, Cetearyl Alcohol, Diheptyl Succinate, Xanthan Gum, Boswellia Serrata Resin Extract, Safflower (Carthamus Tinctorius) Seed Oil, Hemp (Cannabis Sativa) Seed Oil, Marula (Sclerocarya Birrea) Seed Oil, Argan (Argania Spinosa) Kernel Oil, Tocopheryl Acetate, Camphor, Peppermint (Mentha Piperita) Oil, Glyceryl Caprylate, Caprylhydroxamic Acid, Sodium Hydroxide

Sageley Naturals

Extra Strength Pain Relief Cream

Instant Cooling

With 10% Menthol

95% Natural Ingredients

4 FL OZ / 118 ML



EXTRA STRENGTH PAIN RELIEF CREAM

Harness the power of plants with our deeply nourishing blend of botanicals and essential oils. This safe, natural, and highly effective formula provides instant cooling so you can do more of what you love.

HERE'S WHAT'S INSIDE

CAMPHOR

This aromatic oil is extracted from the wood, bark, and root stumps of aged camphor laurels, a species of evergreen trees.



SAFFLOWER

This herbaceous, thistle-like plant is in the same family as sunflowers. Its seeds produce the highly versatile safflower oil.



BOSWELLIA

Otherwise known as Indian frankincense, Boswellia Serrata's herbal extract comes from the tree's bark.



PEPPERMINT

Vibrant peppermint is a crossbreed of watermint and spearmint.



Distributed by Sagely Naturals
Sante Monica, CA 90404
424.262.6614, sagelynaturals.com
info@sagelynaturals.com

*95% of our ingredients can be found in nature or are naturally derived.



EXTRA STRENGTH PAIN RELIEF CREAM



INSTANT COOLING WITH 10% MENTHOL

95% NATURAL INGREDIENTS†
4 FL OZ / 118 ML

Our lightweight cream absorbs quickly — with no greasy residue — and immediately relieves pain. Massage onto sore areas daily or as needed.

UPPER BACK AND SHOULDERS

KNEES

BACK OF NECK

LOWER BACK

ABOUT SAGELY NATURALS

Kaley and Kerrigan launched Sagely Naturals in 2015 with a specific goal in mind: to unearth clean and powerful healing alternatives. Through thoughtful crafting and sourcing, we developed a collection of soothing products that deliver temporary relief from minor aches, pains, and tensions caused by day-to-day life — offering a trusted, welcome approach to whole-body healing.

- MADE IN USA
- NON-GMO
- WOMEN-OWNED
- GLUTEN FREE & VEGAN
- NO PEGS
- NO SULFATES
- NO PARABENS
- NO SYNTHETIC FRAGRANCES

Keep this carton for important Drug Facts information

Drug Facts

Active ingredient Purpose
Menthol 10%Topical analgesic

Uses temporarily relieves the minor aches and pains of muscles and joints associated with: ■ strains ■ bruises ■ simple backache ■ arthritis ■ sprains

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UC-5075

BLEED
DIE LINE

Harness the power of plants with our blend of botanicals and essential oils. This safe, natural, and highly effective formula provides instant cooling so you can do more of what you love.

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Directions

Use only as directed. Adults and children over 12 years: Apply a thin layer to affected area and massage into painful area. Repeat as necessary, but no more than 3 to 4 times daily. Children 12 years or younger: ask a doctor.

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See carton for additional drug facts.
LBL-5070



EXTRA STRENGTH

**PAIN
RELIEF
CREAM**



INSTANT COOLING

WITH 10% MENTHOL

95% NATURAL INGREDIENTS
4 FL OZ / 118 ML

COPY TOLERANCE



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EXTRA STRENGTH PAIN RELIEF CREAM



95% NATURAL INGREDIENTS†

INSTANT COOLING WITH 10% MENTHOL

3 FL OZ / 88 mL

or as needed.

UPPER BACK
AND SHOULDERS

KNEES

BACK OF NECK

LOWER BACK

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UC-5355



EXTRA STRENGTH
**PAIN
RELIEF
CREAM**



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WITH 10% MENTHOL

95% NATURAL INGREDIENTS
3 FL OZ / 88 ML

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See carton for additional drug facts.
TUB-5360

EXTRA STRENGTH PAIN RELIEF CREAM

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82075-415
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
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Inactive Ingredients

Ingredient Name	Strength
SAFFLOWER OIL (UNII: 65UEH262IS)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F)	
ARGAN OIL (UNII: 4V59G5UW9X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82075-415-15	1 in 1 CARTON	07/02/2021	
1		118 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:82075-415-00	1 in 1 CARTON	11/19/2021	
2		88 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	07/02/2021	

Labeler - Sagely Enterprises Inc. (117049032)

Establishment

Name	Address	ID/FEI	Business Operations
Verde Cosmetic Labs, LLC		080656433	manufacture(82075-415)

Revised: 11/2021

Sagely Enterprises Inc.