

DIOLPURE MENTHOL PAIN RELIEF CREAM- menthol, camphor cream
DiolPure, 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.

DiolPure Menthol Pain Relief Cream

Active ingredients

Menthol USP 12%

Camphor 6%

Purpose

Menthol USP 12%.....Topical Analgesic

Camphor 6%.....Topical Analgesic

Uses

for temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises

Warnings

For external use only

Do not use

- on damaged or broken skin

When using this product

- do not bandage tightly
- avoid contact with eyes

Stop use and ask doctor if

- condition worsens or persists
- rash develops

If pregnant or breastfeeding consult your doctor before use.

Keep out of 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:** Consult a doctor

Other information

- Store in a cool, dry place
- Avoid direct sunlight

Inactive ingredients

Arnica Montana, Calendula Officinalis, Cannabidiol, Carbomer, Citric Acid, Ethyl Alcohol, Methyl Glucose Dioleate, Methylsulfonylmethane (MSM), Organic Medium-Chain Triglyceride (MCT), Coconut Oil, Purified Water, Sodium Hydroxide

DiolPure

Menthol 12%

Pain Relief Cream

500MG CBD to moisturize skin

Menthol 12%

For temporary relief of minor aches and pains

Net Wt. 2 oz (56.7 g)

DiolPure

MENTHOL 12%

Pain Relief Cream

DiolPure

MENTHOL 12%

Pain Relief Cream

DiolPure Pain Relief Cream delivers a topical solution for pain relief. DiolPure Pain Relief Cream provides temporary relief for minor aches, as well as, muscle and joint pain associated with backache, arthritis, strains, bruises and sprains. With a combination of cooling menthol, moisturizing CBD, and hydrating emollients, DiolPure Pain Relief Cream will relieve your pain and soothe your skin.

Welcome to DiolPure, daily support for the modern family.

Tested. Proven. Pure.™

www.diolpure.com



DiolPure products are Practitioner-Grade, this means our products are formulated and tested by our team of medical doctors, and are used and endorsed by those same doctors and their families.

500MG CBD to moisturize skin

MENTHOL 12%

For temporary relief of minor aches and pains



Practitioner Grade

Net Wt. 2 oz (56.7 g)

made with **PURE FORM CBD™**

THC FREE

DRUG FACTS

Active Ingredients Purpose
Menthol USP 12%..... Topical Anesthetic
Camphor 6%..... Topical Anesthetic

Uses
For temporary relief of minor aches and pains of muscles and joints associated with:
= simple backache = arthritis = strains = bruises

Warnings
For external use only
Do not use
= on damaged or broken skin
When using this product
= do not bandage tightly = avoid contact with eyes

Stop use and ask doctor if
= condition worsens or persists = rash develops

If pregnant or breastfeeding consult your doctor before use.

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= 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: Consult a doctor

Other Information
= Store in a cool, dry place
= Avoid direct sunlight

Inert Ingredients
Arnica Montana, Calendula Officinalis, Cannabidiol, Carbomer, Citric Acid, Ethyl Alcohol, Methyl Glucose Dioleate, Methylacetylmethane (MSM), Organic Medium-Chain Triglyceride (MCT), Coconut Oil, Purified Water, Sodium Hydroxide

Distributed by: DiolPure USA
Portland, OR 97035
(503) 902-6448
Made in the USA with US and global ingredients



DiolPure

MENTHOL 12%

Pain Relief Cream

500MG CBD to relieve pain

DRUG FACTS

Active Ingredients	Purpose
Menthol USP 12%	Topical Analgesic
Camphor 6%	Topical Analgesic

Uses
For temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises

Warnings
For external use only

Do not use
▪ on damaged or broken skin

MENTHOL 12%

For temporary relief of minor aches and pains

Net Wt. 2 oz. (56.7 g)



Distributed by: DiolPure USA
Portland, OR 97205
(503) 902-9449
Made in the USA with US and global ingredients.
www.diolpure.com

Drug Facts Continued on the next page

DRUG FACTS (Continued)

When using this product
▪ avoid contact with eyes ▪ do not bandage tightly

Stop use and ask doctor if
▪ rash develops ▪ condition worsens or persists

If pregnant or breastfeeding consult your doctor before use.

Keep out of 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: Consult a doctor

hinge area does not print

DRUG FACTS (Continued)

Other Information
▪ Store in a cool, dry place ▪ Avoid direct sunlight

Inactive Ingredients
Arnica Montana, Calendula Officinalis, Cannabinol, Carbomer, Citric Acid, Ethyl Alcohol, Methyl Glucoside, Dioleate, Methylsulfonylmethane (MSM), Organic Medium-Chain Triglyceride (MCT) Coconut Oil, Purified Water, Sodium Hydroxide

hinge area does not print



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menthol, camphor cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82093-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	6 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CANNABIDIOL (UNII: 19GBJ60SN5)	
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ALCOHOL (UNII: 3K9958V90M)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ARNICA MONTANA (UNII: O80TY208ZW)	
WATER (UNII: 059QF0KO0R)	
COCONUT OIL (UNII: Q9L0O73W7L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82093-001-01	1 in 1 CARTON	07/01/2021	
1		56.7 g in 1 BOTTLE, PUMP; 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	07/01/2021	

Labeler - DiolPure, LLC (118147963)

Establishment

Name	Address	ID/FEI	Business Operations
BioLyte Laboratories, LLC		015560564	manufacture(82093-001)

Revised: 7/2021

DiolPure, LLC