

PROLOGEL PAIN RELIEF- camphor (synthetic) and sodium bicarbonate lotion Nova Neura, 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.

ProloGel® Pain Relief

Drug Facts

Active Ingredients*	Purpose
Camphor 0.1%	Topical Analgesic
Sodium Bicarbonate 5%	Skin Protectant

Uses

For relief from

- minor pain
- aches & pains of sore muscles & joints associated with
- arthritis
- backache
- bruises
- strains & sprains.

Warnings

For external use only

- Use only as directed
- Avoid contact with eyes and mucous membranes.
- Do not apply to open wounds or damaged skin.
- Store in cool dry place away from direct sunlight.

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children

If accidentally ingested, get medical help or contact Poison Control Center immediately.

Stop use and ask a doctor if

Condition worsens

- Irritation or redness develops.

Ask doctor before use

If you have sensitive skin.

Directions

Shake well before each use. Keep cap on between uses.

Adults and children 12 years of age or older:

- Apply generous amount to clean, unbroken skin.
- Allow lotion to rest on skin for approximately one minute
- Rub lotion into the target area.
- Reapply up to four times per day.
- Wash hands thoroughly after each application.

Inactive Ingredients*

Behenyl alcohol, Butyrospermum Parkii, Citrus Sinensis Peel Oil, Dimethicone, Disodium EDTA, Emulsifying wax NF, Glycerin, Guar gum, Mannitol, Oleyl alcohol, Polysorbate 20, Purified water, Ricinus Communis (Castor) Seed Oil, Sodium hydroxide, Sorbitan stearate.

Questions or Comments

1 866-516-5508 or Support@ProloGel.com

PRINCIPAL DISPLAY PANEL - 148 mL Bottle Label

ProloGel®

PAIN RELIEF
FORMULA

Clinical Strength
Deep Penetrating
Vanishing Odor

Topical Therapeutic Lotion

Net Wt. 5 oz / 148 mL

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More application suggestions at www.prologel.com. ProloGel is patented with patents pending. ProloGel is a registered trademark ©2020. E Bryan Street #427, Savannah, GA 31401



NDC 77496-101-11



EXP DATE:

LOT#:



PAIN RELIEF

FORMULA



Clinical Strength

Deep Penetrating

Vanishing Odor

Topical Therapeutic Lotion

Net Wt. 5 oz / 148 mL

PROLOGEL PAIN RELIEF

camphor (synthetic) and sodium bicarbonate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77496-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.001 mg in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	0.05 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DOCOSANOL (UNII: 9G1OE216XY)	
SHEA BUTTER (UNII: K49155WL9Y)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	

DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GUAR GUM (UNII: E89I1637KE)	
MANNITOL (UNII: 3OWL53L36A)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
CASTOR OIL (UNII: D5340Y2I9G)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77496-101-11	148 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/01/2020	

Labeler - Nova Neura, LLC (117121636)

Revised: 9/2021

Nova Neura, LLC