PROLOGEL NEUROTHERAPY- 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® Neurotherapy

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, Benfotiamine, Butyrospermum Parkii, Citrus Sinensis Peel Oil, Dimethicone, Disodium ETDA, Emulsfying wax NF, Glycerin, Guar gum, Mannitol, Oleyl alcohol, Polysorbate 20, Pterocarpus Marsupium Bark Extract, Purified water, Ricinus Communis (Castor) Seed Oil, Sodium hydroxide, Sorbitan stearate, Vitamin D.

Questions or Comments

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

PRINCIPAL DISPLAY PANEL - 148 mL Bottle Label

ProloGel[®]

NEUROTHERAPY FORMULA

For Soothing Relief Deep Penetrating Vanishing Odor

Topical Therapeutic Lotion

Net Wt. 5 oz / 148 mL

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Purpose Topical Analgesic

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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, Savanna









NEUROTHERAPY

FORMULA



For Soothing Relief

Deep Penetrating

Vanishing Odor

Topical Therapeutic Lotion

Net Wt. 5 oz / 148 mL

PROLOGEL NEUROTHERAPY

camphor (synthetic) and sodium bicarbonate lotion

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:77496-103

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:HN1Z RA3Q20)	SODIUM BICARBONATE	0.05 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENFOTIAMINE (UNII: Y92OUS2H9B)	
SHEA BUTTER (UNII: K49155WL9Y)	

ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
DIMETHICONE (UNII: 92RU3N3Y10)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GUAR GUM (UNII: E89I1637KE)	
MANNITOL (UNII: 30WL53L36A)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PTEROCARPUS MARSUPIUM WHOLE (UNII: 398N0W54U6)	
WATER (UNII: 059QF0KO0R)	
CASTOR OIL (UNII: D5340Y2I9G)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOSTEARATE (UNII: NVZ 410H58X)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	

Product Characteristics			
Color WHITE Score			
Shape		Size	
Flavor		Imprint Code	
Contains			

l	P	Packaging				
	#	Item Code Package Description Marketing Start Date		Marketing End Date		
	1		148 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/01/2020		

Category Citation Date Date	Marketing Information				
OTC MONOGRAPH			_	Marketing End Date	
FINAL part341 12/01/2020	DGRAPH part341		12/01/2020		

Labeler - Nova Neura, LLC (117121636)

Revised: 9/2021 Nova Neura, LLC