

## **PROLOGEL URGENT CARE- lidocaine 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.*

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**ProloGel® Urgent Care**

### **Drug Facts**

<b>Active Ingredients*</b>	<b>Purpose</b>
Lidocaine 4%	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:**

- Use gloves (or skin barrier) with each application to prevent absorption into hands.
- 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, Citrus Sinensis Peel Oil, Dimethicone, Disodium ETDA, 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](mailto:Support@ProloGel.com)

## **PRINCIPAL DISPLAY PANEL - 148 mL Bottle Carton**

ProloGel®

URGENT CARE  
FORMULA

For Rapid Relief  
Deep Penetrating  
Vanishing Odor

Topical Therapeutic Lotion

Net Wt. 5 oz / 148 mL

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



NDC 77496-102-11



EXP DATE:

LOT#:



# URGENT CARE FORMULA



For Rapid Relief

Deep Penetrating

Vanishing Odor

**Topical Therapeutic Lotion**

Net Wt. 5 oz / 148 mL

## PROLOGEL URGENT CARE

lidocaine and sodium bicarbonate lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77496-102
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 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
DOCOSANOL (UNII: 9G1OE216XY)	
SHEA BUTTER (UNII: K49155WL9Y)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GUAR GUM</b> (UNII: E89I1637KE)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>OLEYL ALCOHOL</b> (UNII: 172F2WN8DV)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77496-102-11	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	part348	12/01/2020	

**Labeler** - Nova Neura, LLC (117121636)