

# NEORELIEF FOR PAIN- topical gel for pain gel

## BioLyte Laboratories, LLC

*Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.*

### Drug Facts Active Ingredients

All active ingredients are HPUS\* and 4X potency

Actaea, Aesculus Hipp., Belladonna, Bryonia., Caulophyllum, Causticum, Cimicifuga, Gaiuacum, Hypericum, Kali Carb., Ledum, Lithium Carb., Rhamnus Calif., Rhododendron, Rhus. Tox., Ruta Grav., Salicylicum Ac., Setllaria Med.

Althaea

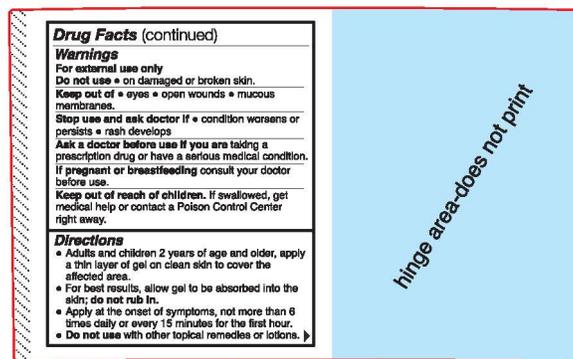
Arnica, Bellis, Calendula

FRONT



← Deline does not print

BACK

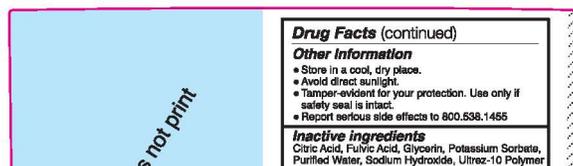


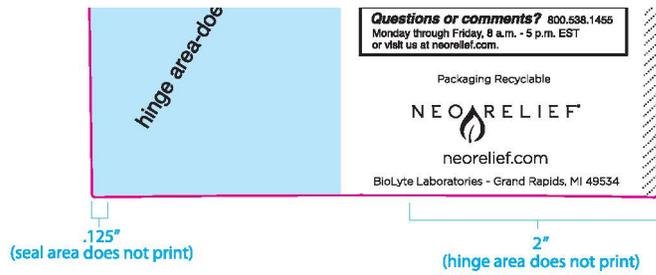
Run Direction →

.125" (seal area does not print)

2" (hinge area does not print)

BASE





**Job No. 129006**  
**3/8/18**



**Western Shield Label Company**  
2146 E. Gladwick Street  
Rancho Dominguez, CA 90220  
www.westernshield.com



**PROOF HISTORY**

1/10/17 Initial proo  
3/8/18 NEW ART Proof

**Client:** BioLyte Labs  
**File Name:** Neo Relief - Pain Relief 2oz ECL  
**Dimension:** 2.77 x 4.5"  
**Corner Radius:** .125" **Die #:** SP 7062  
**Facestock:** 2.6 mil Pearlescent BOPP  
**Coating(s):** 1.0 mil MATTE BOPP LAMINATE

Total Plates: 9

**PLEASE NOTE WELL:** A signed proof is required before your project will be entered into our production schedule. Orders typically ship five (5-7) working days after receipt of an approved proof.

**OK TO PRINT**  **REVISE AND RE-PROOF**



Labels on outside of roll.  
Left-hand side of design  
dispenses first.

**Copy Position #4**

**AUTHORIZED SIGNATURE** \_\_\_\_\_

**DATE** \_\_\_\_\_

By signing this proof, I authorize Western Shield to proceed as indicated above. I understand that this proof, when viewed on a computer or printed on a desktop printer, is not an exact representation of the color, size or quality of the actual printed label. I further understand that I am responsible to inform Western Shield of any omissions or errors on this proof, and Western Shield is not responsible for misspellings, compliance to government regulations, or barcode accuracy.

**Phone: 310.527.6212 • Fax: 310.327.3871**

## Purpose

Topical Analgesics  
Anti-inflammatory  
Relief of bruising and soreness

## Uses

For temporary relief of occasional:  
Minor aches and pains  
Stiffness of muscles, joints, and tissues  
Indications are based on homeopathic materia medica, not clinical tests.

## Warnings

**For external use only**

**Do not use** on damaged or broken skin.

**Keep out of** eyes, open wounds, mucous membranes.

## Warnings

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

## Warnings

**Ask a doctor before use if you are** taking a prescription drug or have a serious medical condition.

## Warnings

**If pregnant or breastfeeding** consult your doctor before use.

## Warnings

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- Adults and children 2 years of age and older, apply a thin layer of gel on clean skin to cover the affected area.
- For best results, allow gel to be absorbed into the skin; **do not rub in.**
- Apply at the onset of symptoms, not more than 6 times daily or every 15 minutes for the first hour.
- **Do not use** with other topical remedies or lotions.

## Other Information

- Store in a cool, dry place.
- Avoid direct sunlight.
- Tamper-evident for your protection. Use only if safety seal is intact.
- Report all serious side effects to 800.538.1455

## Inactive Ingredients

Citric Acid, Fulvic Acid, Glycerin, Potassium Sorbate, Purified Water, Sodium Hydroxide, Ultrez-10 Polymer

## Questions or comments?

800.538.1455

Monday through Friday 8 a.m. - 5 p.m. EST or visit us at [neorelief.com](http://neorelief.com)

## Additional Label Content

Required FTC Disclosure: Product efficacy and claims are based on theories of

homeopathy that are not supported by scientific evidence and most modern allopathic medical professionals.

Made in the USA

Listed with the FDA

(UPC code: 3 58368 00501 5)

Drug Facts continued Peel Here

Packaging Recyclable

neorelief.com

BioLyte laboratories- Grand Rapids, MI 49534

## NEORELIEF for PAIN 56.7g Bottle

NDC 58368-005-01 Patented

NeoRelief

Pain

Temporary relief of minor aches and pains, and stiffness of muscles and joints

Homeopathic

pain relief gel

Net Wt. 2.0 oz (56.7g)

FRONT

NDC 58368-005-01 PATENTED

**NEORELIEF<sup>®</sup>**

**PAIN**  
Temporary relief of minor aches and pains, and stiffness of muscles and joints

Homeopathic pain relief gel  
Net Wt. 2.0 oz (56.7g)

Made in the U.S.A.  
Listed with the FDA  
neorelief.com

**Drug Facts**

Active ingredients	Purpose
All active ingredients are HPUS* & 4X potency. Actaea, Aesculus Hipp., Belladonna, Bryonia, Gaultheria, Gelsemium, Hamamelis, Hydrastis, Hypericum, Kali Carb., Lactum, Lithium Carb., Rhus Tox., Ruta Grav., Sassafras, St. John's Wort, Stevia, Valerian, Yucca.	Topical Analgesics
Althaea.....	
Arnica, Bellis, Calendula.....	Relief of bruising and soreness

\*HPUS indicates the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

**Uses** For temporary relief of occasional:  
• Minor aches and pains. • Stiffness of muscles, joints and tissues. Indications are based on homeopathic materia medica, not clinical tests.

Product efficacy and claims are based on theories of homeopathy that are not supported by scientific evidence and most modern allopathic medical professionals.

Drug Facts continued peel here

← Dieline does not print

BACK

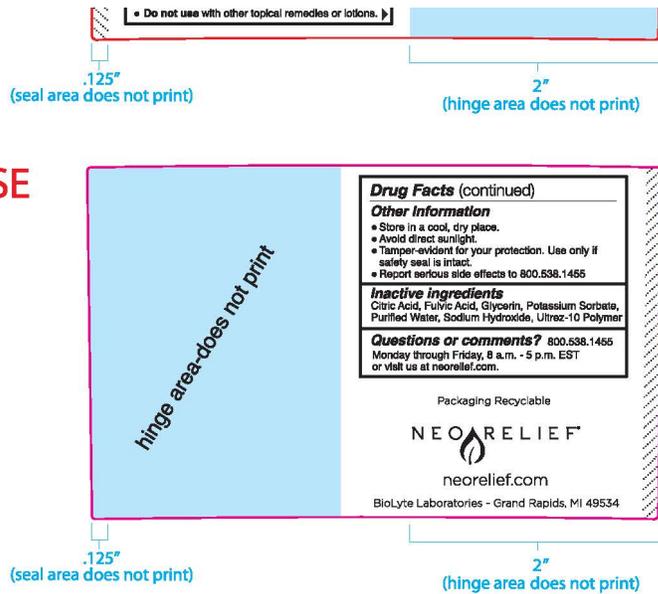
**Drug Facts (continued)**

**Warnings**  
For external use only  
Do not use • on damaged or broken skin.  
Keep out of • eyes • open wounds • mucous membranes.  
Stop use and ask doctor if • condition worsens or persists • rash develops  
Ask a doctor before use if you are taking a prescription drug or have a serious medical condition.  
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 right away.

**Directions**  
• Adults and children 2 years of age and older, apply a thin layer of gel on clean skin to cover the affected area.  
• For best results, allow gel to be absorbed into the skin; do not rub in.  
• Apply at the onset of symptoms, not more than 6 times daily or every 15 minutes for the first hour.

hinge area does not print

Run Direction →



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3/8/18



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## NEORELIEF FOR PAIN

topical gel for pain gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58368-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BELLIS PERENNIS</b> (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	4 [hp_X] in 1 g
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	4 [hp_X] in 1 g
<b>CALENDULA OFFICINALIS FLOWERING TOP</b> (UNII: 18E7415PXQ) (CALENDULA	CALENDULA OFFICINALIS	4 [hp_X]

OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	FLOWERING TOP	in 1 g
<b>CAULOPHYLLUM THALICTROIDES ROOT</b> (UNII: JTJ6HH6YEH) (CAULOPHYLLUM THALICTROIDES ROOT - UNII:JTJ6HH6YEH)	CAULOPHYLLUM THALICTROIDES ROOT	4 [hp_X] in 1 g
<b>CAUSTICUM</b> (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	4 [hp_X] in 1 g
<b>GUAIAACUM OFFICINALE RESIN</b> (UNII: N0K2Z502R6) (GUAIAACUM OFFICINALE RESIN - UNII:N0K2Z502R6)	GUAIAACUM OFFICINALE RESIN	4 [hp_X] in 1 g
<b>HYPERICUM PERFORATUM</b> (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	4 [hp_X] in 1 g
<b>LITHIUM CARBONATE</b> (UNII: 2BMD2GNA4V) (LITHIUM CATION - UNII:8H8Z5UER66)	LITHIUM CARBONATE	4 [hp_X] in 1 g
<b>FRANGULA CALIFORNICA BARK</b> (UNII: 1LZ13MQR0S) (FRANGULA CALIFORNICA BARK - UNII:1LZ13MQR0S)	FRANGULA CALIFORNICA BARK	4 [hp_X] in 1 g
<b>RHODODENDRON AUREUM LEAF</b> (UNII: IV92NQJ73U) (RHODODENDRON AUREUM LEAF - UNII:IV92NQJ73U)	RHODODENDRON AUREUM LEAF	4 [hp_X] in 1 g
<b>TOXICODENDRON PUBESCENS LEAF</b> (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	4 [hp_X] in 1 g
<b>RUTA GRAVEOLENS FLOWERING TOP</b> (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	4 [hp_X] in 1 g
<b>HORSE CHESTNUT</b> (UNII: 3C18L6RJAZ) (HORSE CHESTNUT - UNII:3C18L6RJAZ)	HORSE CHESTNUT	4 [hp_X] in 1 g
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	4 [hp_X] in 1 g
<b>BLACK COHOSH</b> (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	4 [hp_X] in 1 g
<b>STELLARIA MEDIA</b> (UNII: 2H03479QVR) (STELLARIA MEDIA - UNII:2H03479QVR)	STELLARIA MEDIA	4 [hp_X] in 1 g
<b>ACTAEA SPICATA ROOT</b> (UNII: 3FU86L9OS0) (ACTAEA SPICATA ROOT - UNII:3FU86L9OS0)	ACTAEA SPICATA ROOT	4 [hp_X] in 1 g
<b>ALTHAEA OFFICINALIS ROOT</b> (UNII: TRW2FUF47H) (ALTHAEA OFFICINALIS ROOT - UNII:TRW2FUF47H)	ALTHAEA OFFICINALIS ROOT	4 [hp_X] in 1 g
<b>ARNICA MONTANA</b> (UNII: O80TY208Z W) (ARNICA MONTANA - UNII:O80TY208Z W)	ARNICA MONTANA	4 [hp_X] in 1 g
<b>ATROPA BELLADONNA ROOT</b> (UNII: 6MW97Q6E8M) (ATROPA BELLADONNA ROOT - UNII:6MW97Q6E8M)	ATROPA BELLADONNA ROOT	4 [hp_X] in 1 g
<b>POTASSIUM CARBONATE</b> (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	4 [hp_X] in 1 g
<b>LEDUM PALUSTRE TWIG</b> (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWG	4 [hp_X] in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FULVIC ACID</b> (UNII: XII14C5FXV)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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<b>1</b>	NDC:58368-005-01	1 in 1 CARTON	02/01/2017	
<b>1</b>		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
unapproved homeopathic		02/01/2017	

**Labeler** - BioLyte Laboratories, LLC (015560564)

## Establishment

Name	Address	ID/FEI	Business Operations
BioLyte Laboratories, LLC		015560564	manufacture(58368-005)

Revised: 1/2026

BioLyte Laboratories, LLC