

**NEORELIEF FOR MUSCLE CRAMPLING AND RESTLESSNESS- topical gel for muscle cramping and restlessness 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\*

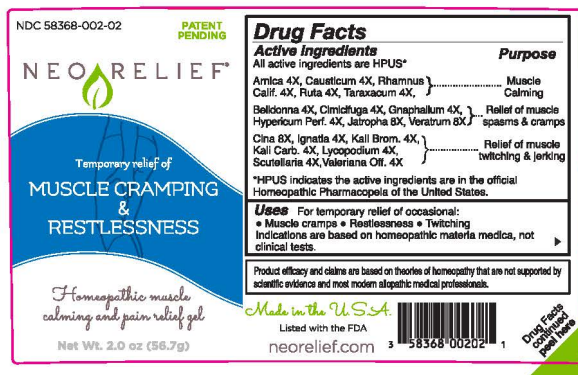
Arnica 4X, Causticum 4X, Rhamnus Calif. 4X, Ruta 4X, Taraxacum 4X,

Belladonna 4X, Cimicifuga 4X, Gnaphalium 4X, Hypericum Perf. 4X, Jatropha 8X, Veratrum 8X

Cina 8X, Ignatia 4X, Kali Brom. 4X, Kali Carb. 4X, Lycopodium 4X, Scutellaria 4X, Valeriana Off. 4X

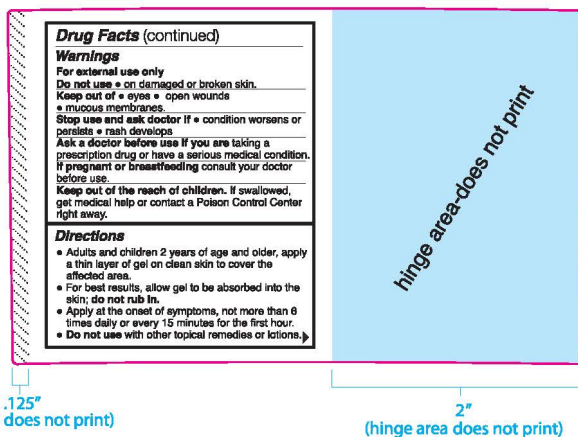
\*HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States.

**FRONT**



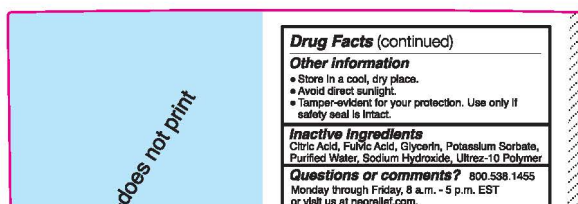
← Dieline does not print

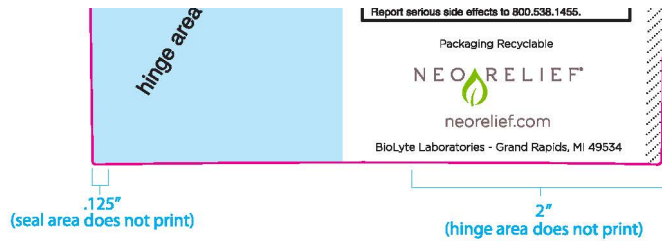
**BACK**



Run Direction →

**BASE**





Job No. **129006**  
2/26/18



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



**PROOF HISTORY**

1/10/17 Initial proo  
2/26/18 NEW ART Proof

**Client:** BioLyte Labs

Total Plates: 10

**File Name:** Neo Relief - Muscle Cramping 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

**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

For the temporary relief of occasional:

Muscle cramps, restlessness, twitching

Indications are based on homeopathic materia medica, not clinical tests.

## Uses

For temporary relief of occasional muscle cramps, restlessness and twitching

## 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 breast-feeding, consult your doctor before use.

### **Warnings**

Keep out of the 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.

### **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)

Report serious side effects to 800.538.1455

### **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 00202 1)

Drug Facts continued peel here

Packaging Recyclable

[neorelief.com](http://neorelief.com)

BioLyte Laboratories- Grand Rapids, MI 49534

**NEORELIEF for Muscle Cramping and Restlessness 56.7 g Bottle**

NDC 58368-002-02 Patent pending

NeoRelief

Temporary relief of muscle cramping and restlessness

Homeopathic muscle calming and pain relief gel

Net Wt. 2.0 oz (56.7g)

FRONT

NDC 58368-002-02 PATENT PENDING

**NEORELIEF**  
Temporary relief of  
**MUSCLE CRAMPING & RESTLESSNESS**  
Homeopathic muscle calming and pain relief gel  
Net Wt. 2.0 oz (56.7g)

**Drug Facts**  
**Active Ingredients**  
All active ingredients are HPUS\*  
Arnica 4X, Causticum 4X, Rhus 4X, } Muscle Calming  
Calif. 4X, Ruta 4X, Taraxacum 4X, }  
Beldonna 4X, Cimicifuga 4X, Gnaphalium 4X, } Relief of muscle  
Hypericum Perf. 4X, Jatropha 8X, Veratrum 8X } spasms & cramps  
Cina 8X, Ignatia 4X, Kali Brom. 4X, } Relief of muscle  
Kali Carb. 4X, Lycopodium 4X, } twitching & jerking  
Scutellaria 4X, Valeriana Off. 4X }  
\*HPUS indicates the active ingredients are in the official homeopathic Pharmacopoeia of the United States.  
**Uses** For temporary relief of occasional:  
• Muscle cramps • Restlessness • Twitching  
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.  
Made in the U.S.A.  
Listed with the FDA  
neorelief.com 3 58368 00202 1 Dry, Fast, Pain Free

← 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 the 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.

hinge area does not print

Run Direction →

.125" (seal area does not print)

2" (hinge area does not print)

BASE

hinge area does not print

**Drug Facts (continued)**  
**Other information**  
• Store in a cool, dry place.  
• Avoid direct sunlight.  
• Tamper-evident for your protection. Use only if safety seal is intact.  
**Inactive ingredients**  
Citric Acid, Fumaric Acid, Glycerin, Potassium Sorbate, Purified Water, Sodium Hydroxide, Ultra-10 Polymer.  
**Questions or comments?** 800.538.1455  
Monday through Friday, 8 a.m. - 5 p.m. EST or visit us at neorelief.com.  
Report serious side effects to 800.538.1455.  
Packaging Recyclable  
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neorelief.com  
BioLyte Laboratories - Grand Rapids, MI 49534

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2" (hinge area does not print)

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

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

DATE \_\_\_\_\_

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## NEORELIEF FOR MUSCLE CRAMPLING AND RESTLESSNESS

topical gel for muscle cramping and restlessness gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58368-002
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	4 [hp_X] in 1 g
JATROPHA CURCAS SEED (UNII: J0F5GM8LA8) (JATROPHA CURCAS SEED - UNII:J0F5GM8LA8)	JATROPHA CURCAS SEED	8 [hp_X] in 1 g
FRANGULA CALIFORNICA BARK (UNII: 1LZ13MQR0S) (FRANGULA CALIFORNICA BARK - UNII:1LZ13MQR0S)	FRANGULA CALIFORNICA BARK	4 [hp_X] in 1 g
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	4 [hp_X] in 1 g
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	4 [hp_X] in 1 g
ATROPA BELLADONNA ROOT (UNII: 6MW97Q6E8M) (ATROPA BELLADONNA ROOT - UNII:6MW97Q6E8M)	ATROPA BELLADONNA ROOT	4 [hp_X] in 1 g
BLACK COHOSH (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	4 [hp_X] in 1 g
ARTEMISIA CINA PRE-FLOWERING TOP (UNII: 28M1820ACT) (ARTEMISIA CINA PRE-FLOWERING TOP - UNII:28M1820ACT)	ARTEMISIA CINA PRE-FLOWERING TOP	8 [hp_X] in 1 g
PSEUDOGNAPHALIUM OBTUSIFOLIUM (UNII: 36XQ854NWW) (PSEUDOGNAPHALIUM OBTUSIFOLIUM - UNII:36XQ854NWW)	PSEUDOGNAPHALIUM OBTUSIFOLIUM	4 [hp_X] in 1 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	4 [hp_X] in 1 g
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	4 [hp_X] in 1 g
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	4 [hp_X] in 1 g
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ50PE7D)	POTASSIUM CARBONATE	4 [hp_X] in 1 g
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	4 [hp_X] in 1 g
SCUTELLARIA LATERIFLORA (UNII: 7BP4DH5PDC) (SCUTELLARIA LATERIFLORA - UNII:7BP4DH5PDC)	SCUTELLARIA LATERIFLORA	4 [hp_X] in 1 g

<b>TARAXACUM OFFICINALE</b> (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	4 [hp_X] in 1 g
<b>VALERIAN</b> (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	8 [hp_X] in 1 g
<b>VERATRUM ALBUM ROOT</b> (UNII: QNS6W5US1Z) (VERATRUM ALBUM ROOT - UNII:QNS6W5US1Z)	VERATRUM ALBUM ROOT	8 [hp_X] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FULVIC ACID</b> (UNII: XIII4C5FXV)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58368-002-02	56.7 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/01/2017	

### 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(58368-002) , pack(58368-002) , label(58368-002)

Revised: 4/2018

BioLyte Laboratories, LLC