NORELIEF 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.

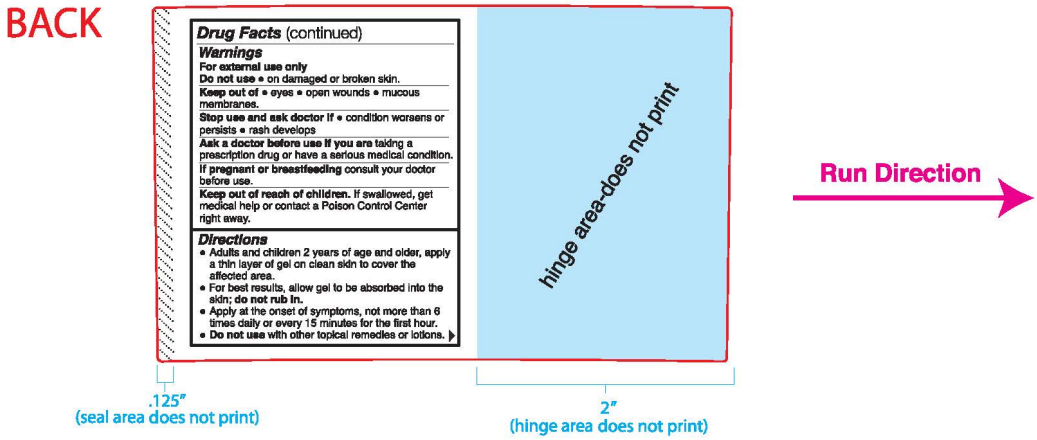
Drug Facts Active Ingredients

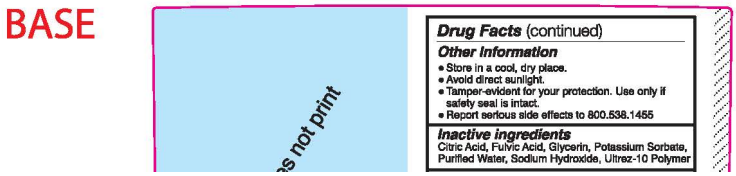
All active ingredients are HPUS* and 4X potency

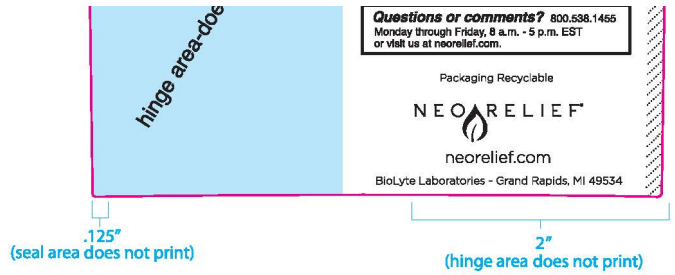
Actaea, Aesculus Hipp., Belladonna, Bryonia., Caulophyllum, Causticum, Cimicifuga, Gauiacum, Hypericum, Kali Carb., Ledum, Lithium Carb., Rhamnus Calif., Rhododendron, Rhus. Tox., Ruta Grav., Salicylicum Ac., Setllaria Med.

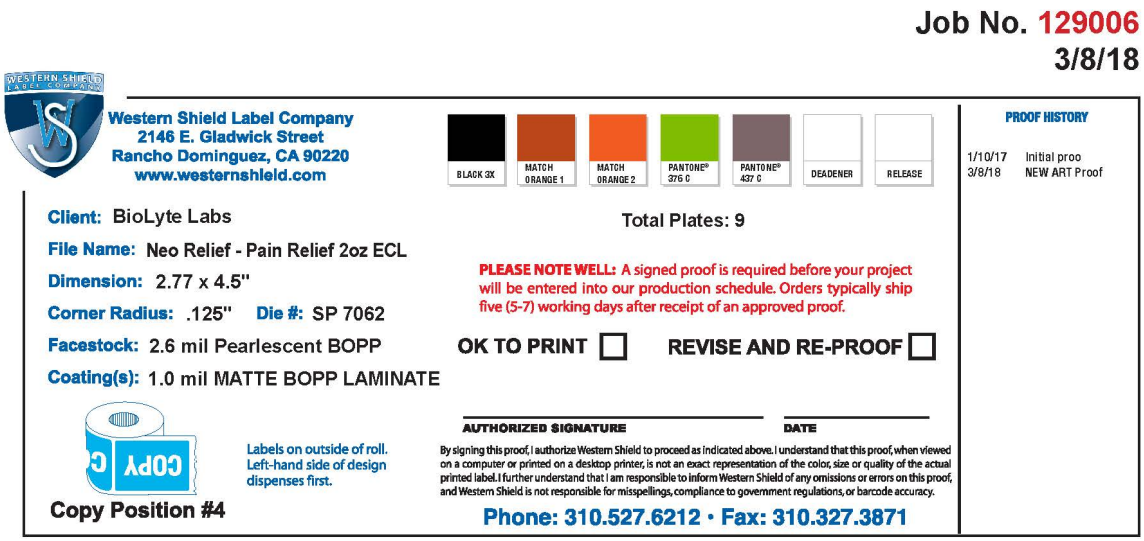
Althaea

Arnica, Bellis, Calendula









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 develeops

Warnings

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

Warnings

If pregnant or breatfeeding 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

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

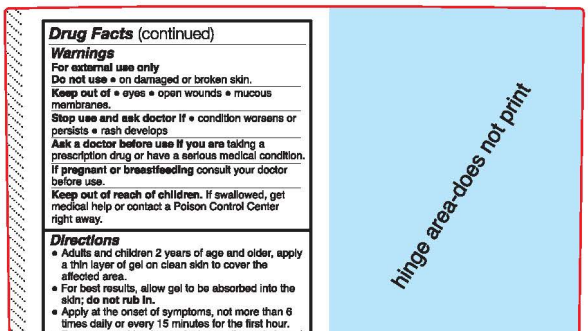
pain relief gel

Net Wt. 2.0 oz (56.7g)

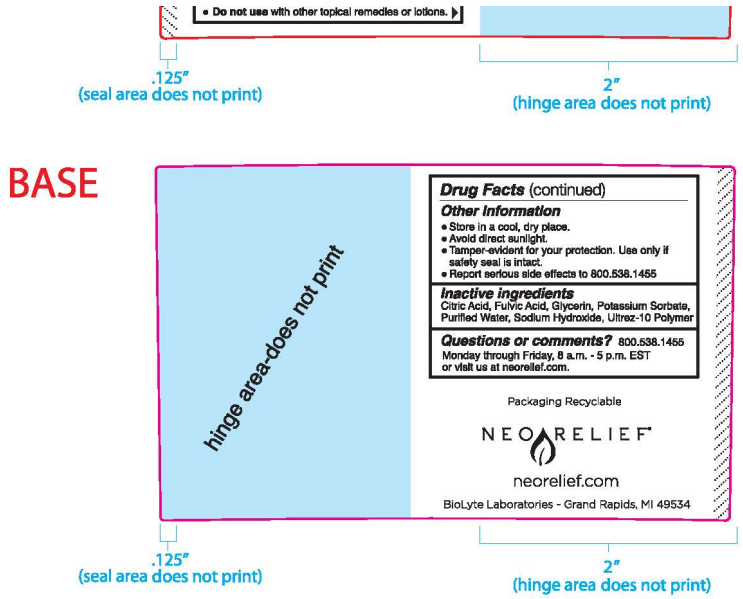
FRONT

← Dieline does not print

BACK



Run Direction →



Job No. 129006
3/8/18

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

BLACK 3X | MATCH ORANGE 1 | MATCH ORANGE 2 | PANTONE® 376 C | PANTONE® 437 C | DEADENER | RELEASE

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 ☐

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

COPY

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

Copy Position #4

NEORELIEF FOR PAIN

topical gel for pain gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58368-005
Route of Administration	TOPICAL		

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

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:58368-005-01	1 in 1 CARTON	02/01/2017	
1		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: 1/2024 BioLyte Laboratories, LLC