

NEORELIEF WOUND CARE- homeopathic healing cream cream

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 actives are HPUS* and 3X potency.

Aesculus Hipp., Calendula Off., Equisetum Arv., Symphytum Off.

Salix Alba, Setllaria Med.

Mezereum Off., Urtica Urens

Althaea Off., Hamamelis Vir.

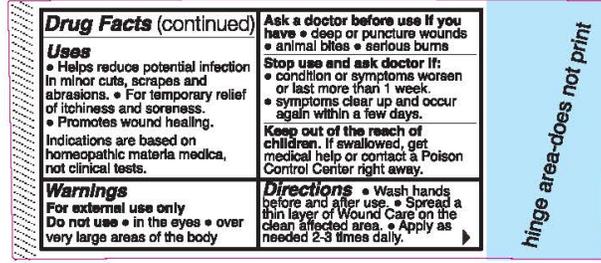
*HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States.

FRONT



← Dieline does not print

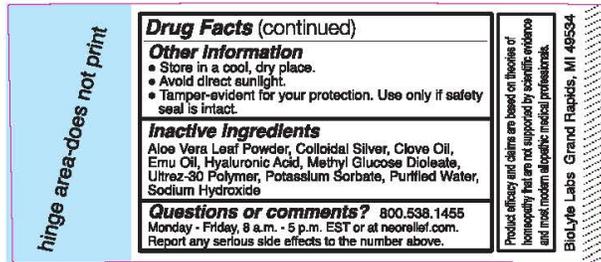
BACK



.125" (seal area does not print)

.75" (hinge area does not print)

BASE



.75" (hinge area does not print)

.125" (seal area does not print)

Job No. **129006**
2/22/18



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

UNWIND DIRECTION →



PROOF HISTORY

2/22/17 Initial proof
2/22/18 NEW ART Proof

Client: BioLyte Labs
File Name: Neo Relief For Wound Care .5oz ECL
Dimension: 1.5711 x 3.6319"
Corner Radius: n/a **Die #:** SP 7064
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**



Copy Position #4

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

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

Promotes Wound Healing

Topical Analgesics

Reduces Itching

Anti-inflammatory

Uses

Helps reduce potential infection in minor cuts, scrapes and abrasions.

For the temporary relief of itchiness and soreness.

Promotes wound healing.

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

Warnings

For external use only.

Do not use in the eyes, over very large areas of the body.

Warnings

Ask a doctor before use if you have deep or puncture wounds, animal bites, serious burns.

Warnings

Stop use and ask doctor if condition or symptoms worsen or last more than 1 week; symptoms clear up and occur again within a few days.

Warnings

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

Directions

Wash hands before and after use; spread a thin layer of Wound Care on the clean affected area; Apply as needed 2-3 times daily.

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

Aloe Vera Leaf Powder, Colloidal Silver, Clove Oil, Emu Oil, Hyaluronic Acid, Methyl Glucose Diolate, Ultrez-30 Polymer, Potassium Sorbate, Purified Water, Sodium Hydroxide

Questions or Comments?

800.538.1455

Monday-Friday, 8 a.m. - 5 p.m. EST or at neorelief.com.

Report any serious side effects to the number above.

Additional Label Content

Packaging Recyclable

Made in the USA

Listed with the FDA

neorelief.com

Drug Facts peeled here

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.

BioLyte Labs Grand Rapids, MI 49534

NEO RELIEF WOUND CARE

NDC 58368-006-06

NEO RELIEF

WOUND CARE

Homeopathic healing cream

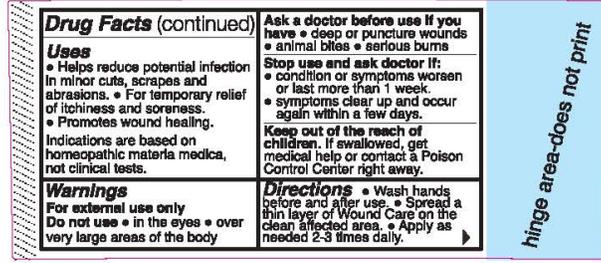
Net Wt. 0.5 oz (14.17g)

FRONT



← Dieline does not print

BACK



.125" (seal area does not print)

.75" (hinge area does not print)

BASE



.75" (hinge area does not print)

.125" (seal area does not print)

UNWIND DIRECTION →

Job No. **129006**
2/22/18



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



PROOF HISTORY

2/22/17 Initial proof
2/22/18 NEW ART Proof

Client: BioLyte Labs
File Name: Neo Relief For Wound Care .5oz ECL
Dimension: 1.5711 x 3.6319"
Corner Radius: n/a **Die #:** SP 7064
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**



Copy Position #4

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

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

homeopathic healing cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58368-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALIX ALBA BARK (UNII: 205MXS71H7) (SALIX ALBA BARK - UNII:205MXS71H7)	SALIX ALBA BARK	3 [hp_X] in 1 g
STELLARIA MEDIA (UNII: 2H03479QVR) (STELLARIA MEDIA - UNII:2H03479QVR)	STELLARIA MEDIA	3 [hp_X] in 1 g
DAPHNE MEZEREUM BARK (UNII: X2N6E405GV) (DAPHNE MEZEREUM BARK - UNII:X2N6E405GV)	DAPHNE MEZEREUM BARK	3 [hp_X] in 1 g
URTICA URENS (UNII: IHN2NQ5OF9) (URTICA URENS - UNII:IHN2NQ5OF9)	URTICA URENS	2 [hp_X] in 1 g
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) (ALTHAEA OFFICINALIS ROOT - UNII:TRW2FUF47H)	ALTHAEA OFFICINALIS ROOT	3 [hp_X] in 1 g
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	3 [hp_X] in 1 g
HORSE CHESTNUT (UNII: 3C18L6RJAZ) (HORSE CHESTNUT - UNII:3C18L6RJAZ)	HORSE CHESTNUT	3 [hp_X] in 1 g
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	3 [hp_X] in 1 g
EQUISETUM ARVENSE TOP (UNII: 1DP6Y6B65Z) (EQUISETUM ARVENSE TOP - UNII:1DP6Y6B65Z)	EQUISETUM ARVENSE TOP	3 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
METHYL GLUCOSE DIOLATE (UNII: FA9KFJ4Z6P)	
WATER (UNII: 059QF0K00R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SILVER (UNII: 3M4G523W1G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CLOVE OIL (UNII: 578389D6D0)	
EMU OIL (UNII: 344821WD61)	
HYALURONIC ACID (UNII: S270N0TRQY)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58368-006-06	14.17 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/27/2018	

Labeler - BioLyte Laboratories, LLC (015560564)

Establishment

Name	Address	ID/FEI	Business Operations
BioLyte Laboratories, LLC		015560564	manufacture(58368-006) , label(58368-006)

Revised: 11/2018

BioLyte Laboratories, LLC