

**EDEMA- elaps corallinus, apis mel., arsenicum alb., cantharis, cinchona, colchicum, convallaria, crotalus horridus, digitalis, juniperus com., lachesis, merc. viv., naja, nat. carb., nat.sulphuricum, rhus toxicodendron, sambucus nig., strophanthus hispidus, thuja occ., vipera berus, echinacea, lappa, solidago, taraxacum, urtica ur. liquid  
Newton Laboratories, Inc.**

*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.*

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**Edema 4812L**

## **INDICATIONS & USAGE SECTION**

Formulated for symptoms such as skin discoloration, discomfort and swelling.

## **DOSAGE & ADMINISTRATION SECTION**

**Directions:** Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) one to four times daily or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

## **OTC - ACTIVE INGREDIENT SECTION**

Equal parts of Echinacea 11x, Lappa 11x, Solidago 11x, Taraxacum 11x, Urtica ur. 11x, Apis mel. 20x, Arsenicum alb. 20x, Cantharis 20x, Cinchona 20x, Colchicum 20x, Convallaria 20x, Crotalus hor. 20x, Digitalis 20x, Juniperus com. 20x, Lachesis 20x, Merc. viv. 20x, Naja 20x, Nat. carb. 20x, Nat.sulphuricum 20x, Rhus tox. 20x, Sambucus nig. 20x, Strophanthus hisp. 20x, Thuja occ. 20x, Vipera 20x, Elaps 35x.

## **OTC - PURPOSE SECTION**

Formulated for symptoms such as skin discoloration, discomfort and swelling.

## **INACTIVE INGREDIENT SECTION**

**Inactive Ingredients:** USP Purified Water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

## **QUESTIONS SECTION**

**newtonlabs.net - Questions ? 800.448.7256**

Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30013

## **WARNINGS SECTION**

**WARNINGS: Keep out of reach of children. Do not use** if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If **pregnant or breast-feeding**, ask a doctor before use.

## **OTC - PREGNANCY OR BREAST FEEDING SECTION**

If **pregnant or breast-feeding**, ask a doctor before use.

**OTC - KEEP OUT OF REACH OF CHILDREN SECTION**

**Keep out of reach of children.**

**PACKAGE LABEL**

**newtonlabs.net ~ Questions? 800.448.7256**  
 Newton Laboratories, Inc. FDA Est# 1051203 • Conners, GA, 30013  
**Label statements have not been reviewed by the FDA.**

**WARNINGS: Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If pregnant or breast-feeding, ask a doctor before use.**

**NEWTON homeopathics PRO**

NDC# 55714-4812-1

**Edema**

Formulated for symptoms such as skin discoloration, discomfort and swelling.

**1 FL OZ (30 ML)**

Dispensed by health professionals - not sold over-the-counter.  
**Directions:** Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) one to four times daily or as directed by a health professional.  
**Active Ingredients:** Equal parts of Echinacea 11x, Lappa 11x, Solidago 11x, Taraxacum 11x, Urtica ur. 11x, Apis mel. 20x, Arsenicum alb. 20x, Cantharis 20x, Cinchona 20x, Colchicum 20x, Convallaria 20x, Crotalus hor. 20x, Digitalis 20x, Juniperus com. 20x, Lachesis 20x, Merc. viv. 20x, Naja 20x, Nat. carb. 20x, Nat. sulphuricum 20x, Rhus tox. 20x, Sambucus nig. 20x, Strophanthus hisp. 20x, Thuja occ. 20x, Vipera 20x, Elaps 35x.  
**Inactive Ingredients:** USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# R072 Lot#

**EDEMA**

elaps corallinus, apis mel., arsenicum alb., cantharis, cinchona, colchicum, convallaria, crotalus horridus, digitalis, juniperus com., lachesis, merc. viv., naja, nat. carb., nat.sulphuricum, rhus toxicodendron, sambucus nig., strophanthus hispidus, thuja occ., vipera berus, echinacea, lappa, solidago, taraxacum, urtica ur. liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-48 12
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MICRURUS CORALLINUS VENOM</b> (UNII: V0S6H36980) (MICRURUS CORALLINUS VENOM - UNII:V0S6H36980)	MICRURUS CORALLINUS VENOM	35 [hp_X] in 1 mL
<b>APIS MELLIFERA</b> (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	20 [hp_X] in 1 mL
<b>ARSENIC TRIOXIDE</b> (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	20 [hp_X] in 1 mL
<b>LYTTA VESICATORIA</b> (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT)	LYTTA VESICATORIA	20 [hp_X] in 1 mL
<b>CINCHONA OFFICINALIS BARK</b> (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	20 [hp_X] in 1 mL
<b>COLCHICUM AUTUMNALE BULB</b> (UNII: 993QHL78E6) (COLCHICUM AUTUMNALE	COLCHICUM AUTUMNALE	20 [hp_X]

BULB - UNII:993QHL78E6)	BULB	in 1 mL
CONVALLARIA MAJALIS (UNII: QHH4HVF5QE) (CONVALLARIA MAJALIS - UNII:QHH4HVF5QE)	CONVALLARIA MAJALIS	20 [hp_X] in 1 mL
CROTALUS HORRIDUS HORRIDUS VENOM (UNII: YHA2XLJ956) (CROTALUS HORRIDUS HORRIDUS VENOM - UNII:YHA2XLJ956)	CROTALUS HORRIDUS HORRIDUS VENOM	20 [hp_X] in 1 mL
NAJA NAJA VENOM (UNII: ZZ4AG7L7VM) (NAJA NAJA VENOM - UNII:ZZ4AG7L7VM)	NAJA NAJA VENOM	20 [hp_X] in 1 mL
DIGITALIS (UNII: F1T8QT9U8B) (DIGITALIS - UNII:F1T8QT9U8B)	DIGITALIS	20 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	20 [hp_X] in 1 mL
MERCURY (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	20 [hp_X] in 1 mL
SODIUM CARBONATE (UNII: 45P3261C7T) (CARBONATE ION - UNII:7UJQ5OPE7D)	SODIUM CARBONATE	20 [hp_X] in 1 mL
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SODIUM SULFATE	20 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	20 [hp_X] in 1 mL
SAMBUCUS NIGRA FLOWERING TOP (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	20 [hp_X] in 1 mL
STROPHANTHUS HISPIDUS SEED (UNII: MO892VI77K) (STROPHANTHUS HISPIDUS SEED - UNII:MO892VI77K)	STROPHANTHUS HISPIDUS SEED	20 [hp_X] in 1 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	20 [hp_X] in 1 mL
VIPERA BERUS VENOM (UNII: 0ORO6NCA4M) (VIPERA BERUS VENOM - UNII:0ORO6NCA4M)	VIPERA BERUS VENOM	20 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	11 [hp_X] in 1 mL
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3) (ARCTIUM LAPPA ROOT - UNII:597E9B3Z3)	ARCTIUM LAPPA ROOT	11 [hp_X] in 1 mL
SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)	SOLIDAGO VIRGAUREA FLOWERING TOP	11 [hp_X] in 1 mL
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	11 [hp_X] in 1 mL
URTICA URENS (UNII: IHN2NQ5OF9) (URTICA URENS - UNII:IHN2NQ5OF9)	URTICA URENS	11 [hp_X] in 1 mL
JUNIPER BERRY (UNII: O84B5194RL) (JUNIPER BERRY - UNII:O84B5194RL)	JUNIPER BERRY	20 [hp_X] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4812-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/02/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/02/2019	

**Labeler** - Newton Laboratories, Inc. (788793610)

**Registrant** - Newton Laboratories, Inc. (788793610)

**Establishment**

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-4812)

Revised: 12/2020

Newton Laboratories, Inc.