

**EDEMA - FLUID RETENTION- 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.

Edema 2432L

INDICATIONS & USAGE SECTION

Formulated for associated 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 6x, Lappa 6x, Solidago 6x, Taraxacum 6x, urtica ur. 6x, Apis mel. 15x, Arsenicum alb. 15x, Cantharis 15x, Cinchona 15x, Colchicum 15x, Convallaria 15x, Crotalus hor. 15x, Digitalis 15x, Juniperus com.15x, Lachesis 15x, Merc. viv. 15x, Naja 15x, Nat. carb. 15x, Nat.sulphuricum 15x, Rhus tox. 15x, Sambucus nig. 15x, Strophanthus hisp. 15x, Thuja occ. 15x, Vipera 15x, Elaps 30x.

OTC - PURPOSE SECTION

Formulated for associated 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™
 Since 1987

NDC# 55714-2432-1

Edema ~ Fluid Retention

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

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.

Active Ingredients: Equal parts of Echinacea 6x, Lappa 6x, Solidago 6x, Taraxacum 6x, Urtica ur. 6x, Apis mel. 15x, Arsenicum alb. 15x, Cantharis 15x, Cinchona 15x, Colchicum 15x, Convallaria 15x, Crotalus hor. 15x, Digitalis 15x, Juniperus com. 15x, Lachesis 15x, Merc. viv. 15x, Naja 15x, Nat. carb. 15x, Nat. sulphuricum 15x, Rhus tox. 15x, Sambucus nig. 15x, Strophanthus hisp. 15x, Thuja occ. 15x, Vipera 15x, Elaps 30x.

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

Stock# **N065** Lot#

1 FL OZ (30 ML)

EDEMA - FLUID RETENTION

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2432
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICRURUS CORALLINUS VENOM (UNII: V0S6H36980) (MICRURUS CORALLINUS VENOM - UNII:V0S6H36980)	MICRURUS CORALLINUS VENOM	30 [hp_X] in 1 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	15 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT)	LYTTA VESICATORIA	15 [hp_X] in 1 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	15 [hp_X] in 1 mL
COLCHICUM AUTUMNALE BULB (UNII: 993QHL78E6) (COLCHICUM AUTUMNALE	COLCHICUM AUTUMNALE	15 [hp_X]

BULB - UNII:993QHL78E6)	BULB	in 1 mL
CONVALLARIA MAJALIS (UNII: QHH4HVF5QE) (CONVALLARIA MAJALIS - UNII:QHH4HVF5QE)	CONVALLARIA MAJALIS	15 [hp_X] in 1 mL
CROTALUS HORRIDUS VENOM (UNII: YHA2XLJ956) (CROTALUS HORRIDUS HORRIDUS VENOM - UNII:YHA2XLJ956)	CROTALUS HORRIDUS HORRIDUS VENOM	15 [hp_X] in 1 mL
DIGITALIS (UNII: FIT8QT9U8B) (DIGITALIS - UNII:FIT8QT9U8B)	DIGITALIS	15 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 mL
MERCURY (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	15 [hp_X] in 1 mL
NAJA NAJA VENOM (UNII: ZZ4AG7L7VM) (NAJA NAJA VENOM - UNII:ZZ4AG7L7VM)	NAJA NAJA VENOM	15 [hp_X] in 1 mL
SODIUM CARBONATE (UNII: 45P3261C7T) (CARBONATE ION - UNII:7UJQ5OPE7D)	SODIUM CARBONATE	15 [hp_X] in 1 mL
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SODIUM SULFATE	15 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 mL
SAMBUCUS NIGRA FLOWERING TOP (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	15 [hp_X] in 1 mL
STROPHANTHUS HISPIDUS SEED (UNII: MO892VI77K) (STROPHANTHUS HISPIDUS SEED - UNII:MO892VI77K)	STROPHANTHUS HISPIDUS SEED	15 [hp_X] in 1 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	15 [hp_X] in 1 mL
VIPERA BERUS VENOM (UNII: 0ORO6NCA4M) (VIPERA BERUS VENOM - UNII:0ORO6NCA4M)	VIPERA BERUS VENOM	15 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3) (ARCTIUM LAPPA ROOT - UNII:597E9B3Z3)	ARCTIUM LAPPA ROOT	6 [hp_X] in 1 mL
SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)	SOLIDAGO VIRGAUREA FLOWERING TOP	6 [hp_X] in 1 mL
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [hp_X] in 1 mL
URTICA URENS (UNII: IHN2NQ5OF9) (URTICA URENS - UNII:IHN2NQ5OF9)	URTICA URENS	6 [hp_X] in 1 mL
JUNIPER BERRY (UNII: O84B5194RL) (JUNIPER BERRY - UNII:O84B5194RL)	JUNIPER BERRY	15 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2432-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/31/2019	
2	NDC:55714-2432-2	50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/31/2019	08/30/2019
3	NDC:55714-2432-0	15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/31/2019	08/30/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/31/2019	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2432)

Revised: 11/2020

Newton Laboratories, Inc.