

**I-WAKER- apis mellifica, echinacea, hydrastis canadensis, thuja occidentalis, aconitum napellus, agaricus muscarius, allium sativum, aloe, arnica montana, arsenicum album, baptisia tinctoria, belladonna, bryonia, calcarea carbonica, calendula officinalis, capsicum annuum, carduus marianus, hepar sulphuris calcareum, iodium, lachesis mutus, lycopodium clavatum, mercurius vivus, nux vomica, phosphorus, pulsatilla, rhus toxicodendron, salvia officinalis, selenium metallicum, taraxacum officinale, tarentula hispana, 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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## **I-Waker 4838L**

### **INDICATIONS & USAGE SECTION**

Formulated for symptoms such as hypersensitivity, debility, glandular swellings, infections and inflammation.

### **DOSAGE & ADMINISTRATION SECTION**

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) three to four times daily or as directed by a health professional.

### **OTC - ACTIVE INGREDIENT SECTION**

Equal parts of Apis mellifica 6x, Echinacea 6x, Hydrastis canadensis 6x, Thuja occidentalis 6x, Aconitum napellus 15x, Agaricus muscarius 15x, Allium sativum 15x, Aloe 15x, Arnica montana 15x, Arsenicum album 15x, Baptisia tinctoria 15x, Belladonna 15x, Bryonia 15x, Calcarea carbonica 15x, Calendula officinalis 15x, Capsicum annuum 15x, Carduus marianus 15x, Hepar sulphuris calcareum 15x, Iodium 15x, Lachesis mutus 15x, Lycopodium clavatum 15x, Mercurius vivus 15x, Nux vomica 15x, Phosphorus 15x, Pulsatilla 15x, Rhus toxicodendron 15x, Salvia officinalis 15x, Selenium metallicum 15x, Taraxacum officinale 15x, Tarentula hispana 15x, Zincum metallicum 15x, Zingiber officinale 15x, Anthracinum 16x, Azadirachta indica 16x, Influenzinum 30x.

### **OTC - PURPOSE SECTION**

Formulated for symptoms such as hypersensitivity, debility, glandular swellings, infections and inflammation.

### **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 • Conyers, 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.

NDC#  
55714-4838-2

**NEWTON**  
homeopathics™  
**PRO**

**I-Waker**

Formulated for symptoms such as hypersensitivity, debility, glandular swellings, infections and inflammation.

**1.7 FL OZ (50 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) three to four times daily or as directed by a health professional.  
**Active Ingredients:** Equal parts of Apis mel. 6x, Echinacea 6x, Hydrastis 6x, Thuja occ. 6x, Aconitum nap. 15x, Agaricus musc. 15x, Allium sat. 15x, Aloe 15x, Arnica 15x, Arsenicum alb. 15x, Baptisia 15x, Belladonna 15x, Bryonia 15x, Calc. carb. 15x, Calendula 15x, Capsicum 15x, Carduus mar. 15x, Hepar sulph. calc. 15x, Iodium 15x, Lachesis 15x, Lycopodium 15x, Merc. viv. 15x, Nux vom. 15x, Phos. 15x, Pulsatilla 15x, Rhus tox. 15x, Salvia 15x, Selenium 15x, Taraxacum 15x, Tarentula hisp. 15x, Zinc. met. 15x, Zingiber 15x, Anthracinum 16x, Azadirachta 16x, Influenzinum 30x.  
**Inactive Ingredients:** USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# R126 Lot#

## I-WAKER

apis mellifica, echinacea, hydrastis canadensis, thuja occidentalis, aconitum napellus, agaricus muscarius, allium sativum, aloe, amica montana, arsenicum album, baptisia tinctoria, belladonna, bryonia, calcarea carbonica, calendula officinalis, capsicum annuum, carduus marianus, hepar sulphuris calcareum, iodium, lachesis mutus, lycopodium clavatum, mercurius vivus, nux vomica, phosphorus, pulsatilla, rhus toxicodendron, salvia officinalis, selenium metallicum, taraxacum officinale, tarentula hispana, liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-4838
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SELENIUM</b> (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	15 [hp_X] in 1 mL
<b>TARAXACUM OFFICINALE</b> (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	15 [hp_X] in 1 mL
<b>LYCOSA TARANTULA</b> (UNII: 86M454L2TT) (LYCOSA TARANTULA - UNII:86M454L2TT)	LYCOSA TARANTULA	15 [hp_X] in 1 mL
<b>ZINC</b> (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	15 [hp_X] in 1 mL
<b>TOXICODENDRON PUBESCENS LEAF</b> (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 mL
<b>ACONITUM NAPELLUS</b> (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	15 [hp_X] in 1 mL
<b>INFLUENZA A VIRUS</b> (UNII: R9HH0NDE2E) (INFLUENZA A VIRUS - UNII:R9HH0NDE2E)	INFLUENZA A VIRUS	30 [hp_X] in 1 mL
<b>APIS MELLIFERA</b> (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	6 [hp_X] in 1 mL
<b>LYCOPODIUM CLAVATUM SPORE</b> (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 mL
<b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
<b>THUJA OCCIDENTALIS LEAFY TWIG</b> (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	6 [hp_X] in 1 mL
<b>AMANITA MUSCARIA FRUITING BODY</b> (UNII: DIF093I037) (AMANITA MUSCARIA FRUITING BODY - UNII:DIF093I037)	AMANITA MUSCARIA FRUITING BODY	15 [hp_X] in 1 mL
<b>GARLIC</b> (UNII: V1V998DC17) (GARLIC - UNII:V1V998DC17)	GARLIC	15 [hp_X] in 1 mL
<b>ALOE</b> (UNII: V5VD430YW9) (ALOE - UNII:V5VD430YW9)	ALOE	15 [hp_X] in 1 mL
<b>ARNICA MONTANA</b> (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	15 [hp_X] in 1 mL
<b>ARSENIC TRIOXIDE</b> (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
<b>BAPTISIA TINCTORIA ROOT</b> (UNII: 5EF0HM5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HM5WU)	BAPTISIA TINCTORIA ROOT	15 [hp_X] in 1 mL
<b>ATROPA BELLADONNA</b> (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	15 [hp_X] in 1 mL
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
<b>OYSTER SHELL CALCIUM CARBONATE, CRUDE</b> (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	15 [hp_X] in 1 mL
<b>CALENDULA OFFICINALIS FLOWERING TOP</b> (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	15 [hp_X] in 1 mL
<b>CAPSICUM</b> (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	15 [hp_X] in 1 mL
<b>MILK THISTLE</b> (UNII: U946SH95EE) (MILK THISTLE - UNII:U946SH95EE)	MILK THISTLE	15 [hp_X] in 1 mL
<b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	15 [hp_X] in 1 mL

<b>IODINE</b> (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	15 [hp_X] in 1 mL
<b>LACHESIS MUTA VENOM</b> (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 mL
<b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
<b>SAGE</b> (UNII: 065C5D077J) (SAGE - UNII:065C5D077J)	SAGE	15 [hp_X] in 1 mL
<b>INFLUENZA B VIRUS</b> (UNII: 1314JZ2X6W) (INFLUENZA B VIRUS - UNII:1314JZ2X6W)	INFLUENZA B VIRUS	30 [hp_X] in 1 mL
<b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 mL
<b>AZADIRACHTA INDICA BARK</b> (UNII: G580B439YI) (AZADIRACHTA INDICA BARK - UNII:G580B439YI)	AZADIRACHTA INDICA BARK	16 [hp_X] in 1 mL
<b>MERCURY</b> (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	15 [hp_X] in 1 mL
<b>STRYCHNOS NUX-VOMICA SEED</b> (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 mL
<b>GINGER</b> (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	15 [hp_X] in 1 mL
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 mL
<b>BACILLUS ANTHRACIS IMMUNOSERUM RABBIT</b> (UNII: 41LZ22DD4N) (BACILLUS ANTHRACIS IMMUNOSERUM RABBIT - UNII:41LZ22DD4N)	BACILLUS ANTHRACIS IMMUNOSERUM RABBIT	16 [hp_X] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-4838-2	50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/30/2020	
2	NDC:55714-4838-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/13/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/30/2020	

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-4838)

Revised: 3/2024

Newton Laboratories, Inc.