

**COLD HANDS - FEET- histaminum hydrochloricum,thyroidinum, aconitum nap., arsenicum alb., bryonia, cactus, calc. fluor., ceanothus, cinchona, convallaria, digitalis, gelsemium, glonoinum, hydrocoyle, kali carb., lachesis, naja, nat carb., nat mur., nux vom., phosphorus, pullsatilla, rhus toxicodendron, strophanthus hispidus, sulphur, echinacea 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.

Cold Hands 2404L

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 - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

DOSAGE & ADMINISTRATION SECTION

Adults, take 6 drops by mouth 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, Aconitum nap. 15x, Arsenicum alb. 15x, Bryonia 15x, Cactus 15, Calc. fluor. 15x, Ceanothus 15x, Cinchona 15x, Convallaria 15x, Digitalis 15x, Gelsemium 15x, Glonoinum 15x, Histaminum hydrochloricum 15x, Hydrocotyle 15x, Kali carb. 15x, Lachesis 15x, Naja 15x, Nat. carb. 15x, Nat. mur. 15x, Nux vom. 15x, Phos. 15x, Pulsatilla 15x, Rhus tox. 15x, Strophanthus hisp. 15x, Sulphur 15x, Thyroidinum 15x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as dizziness, fatigue, weakness, tingling and numb or cold extremities.

INACTIVE INGREDIENT SECTION

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

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as dizziness, fatigue, weakness, tingling and numb or cold

extremities.

OTC - PREGNANCY OR BREAST FEEDING SECTION

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

PACKAGE LABEL

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

NEWTON homeopathics™
 Since 1987

NDC#
 55714-2404-1

Cold Hands~Feet

Formulated for associated symptoms such as dizziness, fatigue, weakness, tingling and numb or cold extremities.

1 FL OZ (30 ML)

Directions: Adults, take 6 drops by mouth 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, Aconitum nap. 15x, Arsenicum alb. 15x, Bryonia 15x, Cactus 15x, Calc. fluor. 15x, Ceanothus 15x, Cinchona 15x, Convallaria 15x, Digitalis 15x, Gelsemium 15x, Glonoinum 15x, Histaminum hydrochloricum 15x, Hydrocotyle 15x, Kali carb. 15x, Lachesis 15x, Naja 15x, Nat. carb. 15x, Nat. mur. 15x, Nux vom. 15x, Phos. 15x, Pulsatilla 15x, Rhus tox. 15x, Strophanthus hisp. 15x, Sulphur 15x, Thyroidinum 15x.

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

Stock# N052 Lot#

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.

COLD HANDS - FEET

histaminum hydrochloricum,thyroidinum, aconitum nap., arsenicum alb., bryonia, cactus, calc. fluor., ceanothus, cinchona, convallaria, digitalis, gelsemium, glonoinum, hydrocoyle, kali carb., lachesis, naja, nat carb., nat mur., nux vom., phosphorus, pullsatilla, rhus toxicodendron, strophanthus hispidus, sulphur, echinacea liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55714-2404 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|-------------------|
| HISTAMINE DIHYDRO CHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N813) | HISTAMINE DIHYDROCHLORIDE | 15 [hp_X] in 1 mL |
| THYROID, UNSPECIFIED (UNII: 0B4FDL9I6P) (THYROID, UNSPECIFIED - UNII:0B4FDL9I6P) | THYROID, UNSPECIFIED | 15 [hp_X] in 1 mL |
| ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD) | ACONITUM NAPELLUS | 15 [hp_X] in 1 mL |
| ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV) | ARSENIC TRIOXIDE | 15 [hp_X] in 1 mL |

| | | |
|---|--------------------------------|----------------------|
| BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B) | BRYONIA ALBA ROOT | 15 [hp_X] in 1 mL |
| SELENICEREUS GRANDIFLORUS STEM (UNII: 7114SV0MYK) (SELENICEREUS GRANDIFLORUS STEM - UNII:7114SV0MYK) | SELENICEREUS GRANDIFLORUS STEM | 15 [hp_X] in 1 mL |
| CALCIUM FLUORIDE (UNII: O3B55K4YK) (FLUORIDE ION - UNII:Q80VPU408O) | CALCIUM FLUORIDE | 15 [hp_X] in 1 mL |
| CEANOTHUS AMERICANUS LEAF (UNII: 25B1Y14T8N) (CEANOTHUS AMERICANUS LEAF - UNII:25B1Y14T8N) | CEANOTHUS AMERICANUS LEAF | 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 |
| CONVALLARIA MAJALIS (UNII: QHH4HVF5QE) (CONVALLARIA MAJALIS - UNII:QHH4HVF5QE) | CONVALLARIA MAJALIS | 15 [hp_X] in 1 mL |
| DIGITALIS (UNII: F1T8QT9U8B) (DIGITALIS - UNII:F1T8QT9U8B) | DIGITALIS | 15 [hp_X] in 1 mL |
| GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q) | GELSEMIUM SEMPERVIRENS ROOT | 15 [hp_X] in 1 mL |
| NITRO GLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3) | NITROGLYCERIN | 15 [hp_X] in 1 mL |
| CENTELLA ASIATICA (UNII: 7M867G6T1U) (CENTELLA ASIATICA - UNII:7M867G6T1U) | CENTELLA ASIATICA | 15 [hp_X] in 1 mL |
| POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D) | POTASSIUM CARBONATE | 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 |
| 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 CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) | SODIUM CHLORIDE | 15 [hp_X] in 1 mL |
| STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919) | STRYCHNOS NUX-VOMICA SEED | 15 [hp_X] in 1 mL |
| PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W) | PHOSPHORUS | 15 [hp_X] in 1 mL |
| PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV) | PULSATILLA VULGARIS | 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 |
| STROPHANTHUS HISPIDUS SEED (UNII: MO892VI77K) (STROPHANTHUS HISPIDUS SEED - UNII:MO892VI77K) | STROPHANTHUS HISPIDUS SEED | 15 [hp_X] in 1 mL |
| SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 15 [hp_X] in 1 mL |
| ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX) | ECHINACEA, UNSPECIFIED | 6 [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:55714-2404-0 | 15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | 11/08/2018 | 08/01/2019 |

| | | | |
|---|------------------|---|------------|
| 2 | NDC:55714-2404-1 | 30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | 11/08/2018 |
|---|------------------|---|------------|

| Marketing Information | | | |
|------------------------------|---|-----------------------------|---------------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved homeopathic | | 11/08/2018 | |

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

| Establishment | | | |
|---------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Newton Laboratories, Inc. | | 788793610 | manufacture(55714-2404) |

Revised: 11/2020

Newton Laboratories, Inc.