

**BLADDER - KIDNEY- apis mel., berber. vulg., bryonia, cantharis, cinchona, equisetum hyemale, ferrum phosphoricum, gelsemium, juniperus com., pareira, phosphorus, plantago, pulsatilla, sabal, terebinthina, uva-ursi, echinacea, hydrastis, lappa, solidago pellet
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.

Bladder 2389P

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

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

WARNINGS SECTION

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

QUESTIONS SECTION

newtonlabs.net ~ Questions? 800.448.7256

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

INACTIVE INGREDIENT SECTION

Inactive Ingredients: Gluten-free, non-GMO, organic beet-derived sucrose (lactose free) pellets.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as frequent or difficult urination, burning, pain, urgency and the sensation of a full bladder.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Hydrastis 6x, Lappa 6x, Solidago 6x, Apis mel. 15x, Berber. vulg. 15x, Bryonia 15x, Cantharis 15x, Cinchona 15x, Equisetum hyem. 15x, Ferrum phos. 15x, Gelsemium 15x, Juniperus com. 15x, Pareira 15x, Phos. 15x, Plantago 15x, Pulsatilla 15x, Sabal 15x, Terebinthina 15x, Uva-ursi 15x.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 pellets) one to four times daily or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

INDICATIONS & USAGE SECTION

Bladder - Kidney Formulated for associated symptoms such as frequent or difficult urination, burning, pain, urgency and the sensation of a full bladder.

PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est# 1051203 • Conway, 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#
 55714-2389-1

**Bladder ~
 Kidney**

Formulated for associated symptoms such as frequent or difficult urination, burning, pain, urgency and the sensation of a full bladder.

Directions: Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 pellets) one to four times daily or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

Active Ingredients: Equal parts of Echinacea 6x, Hydrastis 6x, Lappa 6x, Solidago 6x, Apis mel. 15x, Berber. vulg. 15x, Bryonia 15x, Cantharis 15x, Cinchona 15x, Equisetum hyem. 15x, Ferrum phos. 15x, Gelsemium 15x, Juniperus com. 15x, Pareira 15x, Phos. 15x, Plantago 15x, Pulsatilla 15x, Sabal 15x, Terebinthina 15x, Uva-ursi 15x.

Inactive Ingredients: Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

Stock# **N010** Lot#

1 OZ (28 G)

BLADDER - KIDNEY

apis mel., berber. vulg., bryonia, cantharis, cinchona, equisetum hyemale, ferrum phosphoricum, gelsemium, juniperus com., pareira, phosphorus, plantago, pulsatilla, sabal, terebinthina, uva-ursi, echinacea, hydrastis, lappa, solidago pellet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55714-2389 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|------------------|
| APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z) | APIS MELLIFERA | 15 [hp_X] in 1 g |
| BERBERIS VULGARIS ROOT BARK (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U) | BERBERIS VULGARIS ROOT BARK | 15 [hp_X] in 1 g |
| BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B) | BRYONIA ALBA ROOT | 15 [hp_X] in 1 g |
| LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT) | LYTTA VESICATORIA | 15 [hp_X] in 1 g |
| CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB) | CINCHONA OFFICINALIS BARK | 15 [hp_X] in 1 g |

| | | |
|---|----------------------------------|------------------|
| EQUISETUM HYEMALE (UNII: 59677RXH25) (EQUISETUM HYEMALE - UNII:59677RXH25) | EQUISETUM HYEMALE | 15 [hp_X] in 1 g |
| FERROSO FERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7) | FERROSO FERRIC PHOSPHATE | 15 [hp_X] in 1 g |
| GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q) | GELSEMIUM SEMPERVIRENS ROOT | 15 [hp_X] in 1 g |
| JUNIPER BERRY (UNII: O84B5194RL) (JUNIPER BERRY - UNII:O84B5194RL) | JUNIPER BERRY | 15 [hp_X] in 1 g |
| CHONDRODENDRON TOMENTOSUM ROOT (UNII: 395A3P448Z) (CHONDRODENDRON TOMENTOSUM ROOT - UNII:395A3P448Z) | CHONDRODENDRON TOMENTOSUM ROOT | 15 [hp_X] in 1 g |
| PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W) | PHOSPHORUS | 15 [hp_X] in 1 g |
| PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U) | PLANTAGO MAJOR | 15 [hp_X] in 1 g |
| PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV) | PULSATILLA VULGARIS | 15 [hp_X] in 1 g |
| SAW PALMETTO (UNII: J7WWH9M8QS) (SAW PALMETTO - UNII:J7WWH9M8QS) | SAW PALMETTO | 15 [hp_X] in 1 g |
| TURPENTINE (UNII: XJ6RUH0O4G) (TURPENTINE - UNII:XJ6RUH0O4G) | TURPENTINE | 15 [hp_X] in 1 g |
| ARCTOSTAPHYLOS UVA-URSI LEAF (UNII: 3M5V3D1X36) (ARCTOSTAPHYLOS UVA-URSI LEAF - UNII:3M5V3D1X36) | ARCTOSTAPHYLOS UVA-URSI LEAF | 15 [hp_X] in 1 g |
| ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX) | ECHINACEA, UNSPECIFIED | 6 [hp_X] in 1 g |
| GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV) | GOLDENSEAL | 6 [hp_X] in 1 g |
| ARCTIUM LAPPAL ROOT (UNII: 597E9B3Z3) (ARCTIUM LAPPAL ROOT - UNII:597E9B3Z3) | ARCTIUM LAPPAL ROOT | 6 [hp_X] in 1 g |
| SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50) | SOLIDAGO VIRGAUREA FLOWERING TOP | 6 [hp_X] in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------|----------|
| SUCROSE (UNII: C151H8M554) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:55714-2389-1 | 28 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | 10/30/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 10/30/2018 | |

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

| Establishment | | | |
|---------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Newton Laboratories, Inc. | | 788793610 | manufacture(55714-2389) |

Revised: 11/2020

Newton Laboratories, Inc.