

**COLD - SINUS- influenza a virus, influenza b virus, aralia quinquefolia, arsenicum alb., bryonia, euphrasia, gaultheria procubens, gelsemium, hepar sulph. calc., histaminum hydrochloricum, hydrastis, kali bic., merc. viv., phosphorus, pulsatilla, rhus toxicodendron, sabadilla, salvia, sticta, verbascum, 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.

ColdSi 2406L

OTC - PURPOSE SECTION

Formulated for associated symptoms such as runny nose, watery eyes, congestion, pain, sinus pressure, post-nasal drip, cough and inflammation.

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

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.

QUESTIONS SECTION

newtonlabs.net - Questions? 800 448-7256

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

INACTIVE INGREDIENT SECTION

USP Purified water, USP Gluten-free, non-GMO, organic cane alcohol 20%.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Hydrastis 6x, Aralia quin. 15x, Arsenicum alb. 15x, Bryonia 15x, Euphrasia 15x, Gaultheria 15x, Gelsemium 15x, Hepar sulph. calc. 15x, Histaminum hydrochloricum 15x, Hydrastis 15x, Kali bic. 15x, Merc. viv. 15x, Phos. 15x, Pulsatilla

15x, Rhus tox. 15x, Sabadilla 15x, Salvia 15x, Sticta 15x, Verbascum 15x, Sinusitisinum 16x, Influenzinum 30x.

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as runny nose, watery eyes, congestion, pain, sinus pressure, post-nasal drip, cough and inflammation.

DOSAGE & ADMINISTRATION SECTION

Ages 12 and up, take 6 drops by mouth (ages 4 to 11, give 3 drops) as needed or as directed by a health professional. Under age 4, consult a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

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# 55714-2406-1

Cold~Sinus

Formulated for associated symptoms such as runny nose, watery eyes, congestion, pain, sinus pressure, post-nasal drip, cough and inflammation.

Directions: Ages 12 and up, take 6 drops by mouth (ages 4 to 11, give 3 drops) as needed or as directed by a health professional. Under age 4, consult a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Equal parts of Echinacea 6x, Hydrastis 6x, Aralia quin. 15x, Arsenicum alb. 15x, Bryonia 15x, Euphrasia 15x, Gaultheria 15x, Gelsemium 15x, Hepar sulph. calc. 15x, Histaminum hydrochloricum 15x, Hydrastis 15x, Kali bic. 15x, Merc. viv. 15x, Phos. 15x, Pulsatilla 15x, Rhus tox 15x, Sabadilla 15x, Salvia 15x, Sticta 15x, Verbascum 15x, Sinusitisinum 16x, Influenzinum 30x.

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

Stock# N003 Lot#

1 FL OZ (30 ML)

COLD - SINUS

influenza a virus, influenza b virus, aralia quinquefolia, arsenicum alb., bryonia, euphrasia, gaultheria procubens, gelsemium, hepar sulph. calc., histaminum hydrochloricum, hydrastis, kali bic., merc. viv., phosphorus, pulsatilla, rhus toxicodendron, sabadilla, salvia, sticta, verbascum, echinacea liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2406
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SINUSITISINUM (UNII: B575563DM5) (SINUSITISINUM - UNII:B575563DM5)	SINUSITISINUM	16 [hp_X] in 1 mL
INFLUENZA A VIRUS (UNII: R9HH0NDE2E) (INFLUENZA A VIRUS - UNII:R9HH0NDE2E)	INFLUENZA A VIRUS	30 [hp_X] in 1 mL
AMERICAN GINSENG (UNII: 8W75VCV53Q) (AMERICAN GINSENG - UNII:8W75VCV53Q)	AMERICAN GINSENG	15 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_C] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
EUPHRASIA STRICTA (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	15 [hp_X] in 1 mL
GAULTHERIA PROCUMBENS TOP (UNII: 830295X963) (GAULTHERIA PROCUMBENS TOP - UNII:830295X963)	GAULTHERIA PROCUMBENS TOP	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
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	15 [hp_X] in 1 mL
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	15 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	15 [hp_X] in 1 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	15 [hp_X] in 1 mL
MERCURY (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	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
SCHOENOCAULON OFFICINALE SEED (UNII: 6NAF1689IO) (SCHOENOCAULON OFFICINALE SEED - UNII:6NAF1689IO)	SCHOENOCAULON OFFICINALE SEED	15 [hp_X] in 1 mL
SAGE (UNII: 065C5D077J) (SAGE - UNII:065C5D077J)	SAGE	15 [hp_X] in 1 mL
LOBARIA PULMONARIA (UNII: D1YM0P5Z2T) (LOBARIA PULMONARIA - UNII:D1YM0P5Z2T)	LOBARIA PULMONARIA	15 [hp_X] in 1 mL
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS	15 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
INFLUENZA B VIRUS (UNII: 1314JZ2X6W) (INFLUENZA B VIRUS - UNII:1314JZ2X6W)	INFLUENZA B VIRUS	30 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2406-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	11/09/2018	
2	NDC:55714-2406-2	50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	11/09/2018	08/01/2019
3	NDC:55714-2406-0	15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	11/09/2018	08/01/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/09/2018	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2406)

Revised: 3/2022

Newton Laboratories, Inc.