

COLD SORES- arsenicum alb., bryonia, cantharis, chelidonium majus, cistus canadensis, conium, croton, dulcamara, graphites, kali bic., lycopodium, mezereum, nux vom., petroleum, pulsatilla, ranunc. bulb., rhus toxicodendron, sarsaparilla, sepia, sulphur, thuja occ., echinacea, hypericum 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.

ColdSo 2408L

INDICATIONS & USAGE SECTION

Formulated for symptoms associated with eruptions and sores of the lips and mouth such as itching, crusting, redness and pain.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed 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, Hypericum 6x, Arsenicum alb. 15x, Bryonia 15x, Cantharis 15x, Chelidonium majus 15x, Cistus canadensis 15x, Conium 15x, Croton 15x, Dulcamara 15x, Graphites 15x, Kali bic.15x, Lycopodium 15x, Mezereum 15x, Nux vom. 15x, Petroleum 15x, Pulsatilla 15x, Ranunc. bulb. 15x, Rhus toxicodendron 15x, Sarsaparilla 15x, Sepia 15x, Sulphur 15x, Thuja occ. 15x.

OTC - PURPOSE SECTION

Formulated for symptoms associated with eruptions and sores of the lips and mouth such as itching, crusting, redness and pain.

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.

NEWTON
homeopathics™
Since 1987

NDC#
55714-2408-1

Cold Sores

Formulated for symptoms associated with eruptions and sores of the lips and mouth such as itching, crusting, redness and pain.

1 FL OZ (30 ML)

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed 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, Hypericum 6x, Arsenicum alb. 15x, Bryonia 15x, Cantharis 15x, Chelidonium maj. 15x, Cistus canadensis 15x, Conium 15x, Croton 15x, Dulcamara 15x, Graphites 15x, Kali bic. 15x, Lycopodium 15x, Mezereum 15x, Nux vom. 15x, Petroleum 15x, Pulsatilla 15x, Ranunc. bulb. 15x, Rhus tox. 15x, Sarsaparilla 15x, Sepia 15x, Sulphur 15x, Thuja occ. 15x.

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

Stock# **N039** Lot#

COLD SORES

arsenicum alb., bryonia, cantharis, chelidonium majus, cistus canadensis, conium, croton, dulcamara, graphites, kali bic., lycopodium, mezereum, nux vom., petroleum, pulsatilla, ranunc. bulb., rhus toxicodendron, sarsaparilla, sepia, sulphur, thuja occ., echinacea, hypericum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2408
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT)	LYTTA VESICATORIA	15 [hp_X] in 1 mL
CHELIDONIUM MAJUS (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	15 [hp_X] in 1 mL
HELIANTHEMUM CANADENSE (UNII: 46G3W789Q3) (HELIANTHEMUM CANADENSE - UNII:46G3W789Q3)	HELIANTHEMUM CANADENSE	15 [hp_X] in 1 mL
CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM	CONIUM MACULATUM	15 [hp_X]

MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	FLOWERING TOP	in 1 mL
CROTON TIGLIUM SEED (UNII: 0HK2GZK66E) (CROTON TIGLIUM SEED - UNII:0HK2GZK66E)	CROTON TIGLIUM SEED	15 [hp_X] in 1 mL
SOLANUM DULCAMARA TOP (UNII: KPS1B1162N) (SOLANUM DULCAMARA TOP - UNII:KPS1B1162N)	SOLANUM DULCAMARA TOP	15 [hp_X] in 1 mL
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	15 [hp_X] in 1 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	15 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 mL
DAPHNE MEZEREUM BARK (UNII: X2N6E405GV) (DAPHNE MEZEREUM BARK - UNII:X2N6E405GV)	DAPHNE MEZEREUM BARK	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
KEROSENE (UNII: 1C89KKC04E) (KEROSENE - UNII:1C89KKC04E)	KEROSENE	15 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 mL
RANUNCULUS BULBOSUS (UNII: AEQ8NXJ0MB) (RANUNCULUS BULBOSUS - UNII:AEQ8NXJ0MB)	RANUNCULUS BULBOSUS	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
SMILAX ORNATA ROOT (UNII: 2H1576D5WG) (SMILAX ORNATA ROOT - UNII:2H1576D5WG)	SMILAX ORNATA ROOT	15 [hp_X] in 1 mL
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	15 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	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
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2408-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

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

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2408)

Revised: 1/2020

Newton Laboratories, Inc.