

**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 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.*

-----  
**Cold Sores**

**INDICATIONS & USAGE SECTION**

**Cold Sores** 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 pellets orally (ages 0 to 11, give 3 pellets) as needed or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

**OTC - ACTIVE INGREDIENT SECTION**

Arsenicum alb. 10x, Bryonia 10x, Cantharis 10x, Chelidonium majus 10x, Cistus canadensis 10x, Conium 10x, Croton 10x, Dulcamara 10x, Graphites 10x, Kali bic.10x, Lycopodium 10x, Mezereum 10x, Nux vom. 10x, Petroleum 10x, Pulsatilla 10x, Ranunc. bulb. 10x, Rhus toxicodendron 10x, Sarsaparilla 10x, Sepia 10x, Sulphur 10x, Thuja occ. 10x, Echinacea 3x, Hypericum 3x.

**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:** Gluten-free, non-GMO, beet-derived sucrose pellets.

**QUESTIONS SECTION**

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012  
Questions? 1.800.448.7256

**WARNINGS SECTION**

**Warning:** Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

**OTC - PREGNANCY OR BREAST FEEDING SECTION**

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for

more than a few days.

## OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

## PACKAGE LABEL

**www.newtonlabs.net**  
Newton Laboratories, Inc. FDA Est#1051203 • Conyers, GA 30012  
**Questions? 1.800.448.7256**  
**Warnings:** Do not use if tamper-evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

**NEWTON**  
*homeopathics*   
Nurturing Naturally Since 1987™  
NDC# 55714-2277-1

**Cold Sores**

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

**1 oz (28.35 g)**

**Directions:** Ages 12 and up, take 6 pellets orally (ages 0 to 11, give 3 pellets) as needed or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

**Active Ingredients:** Arsenicum alb. 10x, Bryonia 10x, Cantharis 10x, Chelidonium majus 10x, Cistus canadensis 10x, Conium 10x, Croton 10x, Dulcamara 10x, Graphites 10x, Kali bic. 10x, Lycopodium 10x, Mezereum 10x, Nux vom. 10x, Petroleum 10x, Pulsatilla 10x, Ranunc. bulb. 10x, Rhus toxicodendron 10x, Sarsaparilla 10x, Sepia 10x, Sulphur 10x, Thuja occ. 10x, Echinacea 3x, Hypericum 3x.

**Inactive Ingredients:** Gluten-free, non-GMO, beet-derived sucrose pellets.

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 pellet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55714-2277
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Arsenic Trioxide</b> (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	10 [hp_X] in 1 g
<b>Bryonia Alba Root</b> (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	10 [hp_X] in 1 g
<b>Lytta Vesicatoria</b> (UNII: 3Q034RO3BT) (Lytta Vesicatoria - UNII:3Q034RO3BT)	Lytta Vesicatoria	10 [hp_X] in 1 g
<b>Chelidonium Majus</b> (UNII: 7E889U5RNN) (Chelidonium Majus - UNII:7E889U5RNN)	Chelidonium Majus	10 [hp_X] in 1 g

<b>Helianthemum Canadense</b> (UNII: 46G3W789Q3) (Helianthemum Canadense - UNII:46G3W789Q3)	Helianthemum Canadense	10 [hp_X] in 1 g
<b>Conium Maculatum Flowering Top</b> (UNII: Q28R5GF371) (Conium Maculatum Flowering Top - UNII:Q28R5GF371)	Conium Maculatum Flowering Top	10 [hp_X] in 1 g
<b>Croton Tiglium Seed</b> (UNII: 0HK2GZK66E) (Croton Tiglium Seed - UNII:0HK2GZK66E)	Croton Tiglium Seed	10 [hp_X] in 1 g
<b>Solanum Dulcamara Top</b> (UNII: KPS1B1162N) (Solanum Dulcamara Top - UNII:KPS1B1162N)	Solanum Dulcamara Top	10 [hp_X] in 1 g
<b>Graphite</b> (UNII: 4QQN74LH4O) (Graphite - UNII:4QQN74LH4O)	Graphite	10 [hp_X] in 1 g
<b>Potassium Dichromate</b> (UNII: T4423S18FM) (Dichromate Ion - UNII:9LKY4BFN2V)	Potassium Dichromate	10 [hp_X] in 1 g
<b>Lycopodium Clavatum Spore</b> (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	10 [hp_X] in 1 g
<b>Daphne Mezereum Bark</b> (UNII: X2N6E405GV) (Daphne Mezereum Bark - UNII:X2N6E405GV)	Daphne Mezereum Bark	10 [hp_X] in 1 g
<b>Strychnos Nux-vomica Seed</b> (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	10 [hp_X] in 1 g
<b>Kerosene</b> (UNII: 1C89KKC04E) (Kerosene - UNII:1C89KKC04E)	Kerosene	10 [hp_X] in 1 g
<b>Pulsatilla Vulgaris</b> (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	10 [hp_X] in 1 g
<b>Ranunculus Bulbosus</b> (UNII: AEQ8NXJ0MB) (Ranunculus Bulbosus - UNII:AEQ8NXJ0MB)	Ranunculus Bulbosus	10 [hp_X] in 1 g
<b>Toxicodendron Pubescens Leaf</b> (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	10 [hp_X] in 1 g
<b>Smilax Regelii Root</b> (UNII: 2H1576D5WG) (Smilax Regelii Root - UNII:2H1576D5WG)	Smilax Regelii Root	10 [hp_X] in 1 g
<b>Sepia Officinalis Juice</b> (UNII: QDL83WN8C2) (Sepia Officinalis Juice - UNII:QDL83WN8C2)	Sepia Officinalis Juice	10 [hp_X] in 1 g
<b>Sulfur</b> (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70)	Sulfur	10 [hp_X] in 1 g
<b>Thuja Occidentalis Leafy Twig</b> (UNII: 1NT28V9397) (Thuja Occidentalis Leafy Twig - UNII:1NT28V9397)	Thuja Occidentalis Leafy Twig	10 [hp_X] in 1 g
<b>Echinacea, Unspecified</b> (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 g
<b>Hypericum Perforatum</b> (UNII: XK4IUX8MNB) (Hypericum Perforatum - UNII:XK4IUX8MNB)	Hypericum Perforatum	3 [hp_X] in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Sucrose</b> (UNII: C151H8M554)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2277-1	28.35 g in 1 BOTTLE, GLASS		
2	NDC:55714-2277-2	56.7 g in 1 BOTTLE, GLASS		
3	NDC:55714-2277-0	7.08 g in 1 BOTTLE, GLASS		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2011	

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

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2277)

Revised: 3/2011

Newton Laboratories, Inc.