

**4 KIDS COLD AND MUCUS- euphrasia stricta, silicon dioxide, rumex crispus root, anemone pulsatilla, goldenseal, sodium chloride, phosphorus, onion, bryonia alba root, matricaria chamomilla, arabica coffee bean, calcium sulfide and sulfur
Hyland's 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.

4 Kids Cold'n Mucus Value Pack

DAYTIME

Drug Facts

Active ingredients

Bryonia Alba 6X HPUS

Euphrasia Officinalis 6X HPUS

Hepar Sulph Calc 12X HPUS

Natrum Muriaticum 30X HPUS

Phosphorus 30X HPUS

Pulsatilla 6X HPUS

Rumex Crispus 6X HPUS

Silicea 12X HPUS

"HPUS" indicates that the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

Bryonia Alba 6X HPUS...stubborn mucus in throat, cough with yellowish mucus

Euphrasia Officinalis 6X HPUS...cough with mucus in chest

Hepar Sulph Calc 12X HPUS.....cough up mucus, mucus rattle with cough, stubborn mucus in chest

Natrum Muriaticum 30X HPUS.....accumulation of mucus in throat, cough up mucus

Phosphorus 30X HPUS.....cough with expectoration of yellow mucus, chest congestion

Pulsatilla 6X HPUS...accumulation of mucus, discharge of thick yellowish mucus, loose cough

Rumex Crispus 6X HPUS.....runny nose, sneezing

Silicea 12X HPUS.....nasal congestion

Uses

Temporarily relieves symptoms of colds, including accumulation of mucus in chest, throat and nose; cough with expectoration of thick, discolored mucus; runny nose, sneezing and nasal congestion.

Warnings

As with any drug, ask a doctor before use if pregnant or breast-feeding.

Consult a physician if:

- symptoms persist for more than 7 days or worsen.
- inflammation, fever or infection develops.
- symptoms are accompanied by a high fever (over 101°F).
- cough tends to recur or is accompanied by a high fever, rash or persistent headache.

Keep this and all medications out of the reach of children. In case of accidental overdose, contact a medical professional or Poison Control Center immediately.

Do not use this product for persistent or chronic cough such as asthma, smoking or emphysema or if cough is accompanied by excessive mucus, unless directed by a licensed health care professional.

A persistent cough may be a sign of a serious condition.

Sore throat warning

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.

Do not use if imprinted tamper-evident bottle band is broken or missing.

The inner packaged bottle is child-resistant. In case of emergency, contact a medical professional or Poison Control Center immediately. Hyland's may also be contacted for emergency information about our products 24 hours a day, 7 days per week at (800) 624-9659.

Drug Facts (continued)

Directions

- Measure only with the dosing cup provided
- Do not use dosing cup with other products
- On dosing cup, mL = milliliter, tsp = teaspoon

Children 2 years to under 6 years	5 mL or 1 teaspoon up to 6 times per day (every 4 hours)
Children 6 years to under 12 years	10 mL or 2 teaspoons up to 6 times per day (every 4 hours)
Adults and children 12 years and over	15 mL or 3 teaspoons up to 6 times per day (every 4 hours)

Inactive ingredients

Citric Acid, Glycerine, Glycyrrhiza Extract, Purified Water, Sodium Benzoate.

NIGHTTIME

Active ingredients

Allium Cepa 6X HPUS

Bryonia Alba 6X HPUS

Chamomilla 3X HPUS

Coffea Cruda 3X HPUS

Euphrasia Officinalis 6X HPUS

Hepar Sulph Calc 12X HPUS

Hydrastis 6X HPUS

Natrum Muriaticum 6X HPUS

Phosphorus 30X HPUS

Pulsatilla 6X HPUS

Rumex Crispus 6X HPUS

Silicea 12X HPUS

Sulphur 12X HPUS

"HPUS" indicates that the active ingredients are in the official Homeopathic Pharmacopœia of the United States.

Allium Cepa 6X HPUS.....runny nose with mucus, hacking cough, sore throat

Bryonia Alba 6X HPUS...stubborn mucus in throat, cough with yellowish mucus

Chamomilla 3X HPUS.....irritability, fussiness, occasional sleeplessness

Coffea Cruda 3X HPUS.....occasional sleeplessness, restlessness

Euphrasia Officinalis 6X HPUS...cough with mucus in chest

Hepar Sulph Calc 12X HPUS.....cough up mucus, mucus rattle with cough, stubborn mucus in chest

Hydrastis 6X HPUS...cough with mucus, dry, sore throat, occasional sleeplessness due to mucus in throat

Natrum Muriaticum 6X HPUS...accumulation of mucus in throat, cough up mucus

Phosphorus 30X HPUS.....cough with expectoration of yellow mucus, chest congestion

Pulsatilla 6X HPUS...accumulation of mucus, discharge of thick yellowish mucus, loose cough

Rumex Crispus 6X HPUS.....runny nose, sneezing

Silicea 12X HPUS.....nasal congestion

Sulphur 12X HPUS.....cough with thick mucus, chest congestion, nasal congestion

Uses

Temporarily relieves the symptoms of the common cold in children especially at night including accumulation of mucus in chest, throat and nose, cough with mucus, runny nose, sneezing, nasal congestion and occasional sleeplessness.

Drug Facts (continued)

Warnings

As with any drug, ask a doctor before use if pregnant or breast-feeding.

Consult a physician if:

- symptoms persist for more than 7 days or worsen.
- inflammation, fever or infection develops.
- symptoms are accompanied by a high fever (over 101°F).
- cough tends to recur or is accompanied by a high fever, rash or persistent headache.

Keep this and all medications out of the reach of children. In case of accidental overdose, contact a medical professional or Poison Control Center immediately.

Do not use this product for persistent or chronic cough such as asthma, smoking or emphysema or if cough is accompanied by excessive mucus, unless directed by a licensed health care professional.

A persistent cough may be a sign of a serious condition.

Sore throat warning

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.

Do not use if imprinted tamper-evident bottle band is broken or missing.

The inner packaged bottle is child-resistant. In case of emergency, contact a medical professional or Poison

Control Center immediately. Hyland's may also be contacted for emergency information about our products

24 hours a day, 7 days per week at (800) 624-9659.

Directions

- Measure only with the dosing cup provided
- Do not use dosing cup with other products
- On dosing cup, mL = milliliter, tsp = teaspoon

Children 2 years
to under 6 years

5 mL or 1 teaspoon at bedtime
and every 4 hours during the
night or as necessary

Children 6 years to under 12 years	10 mL or 2 teaspoons at bedtime and every 4 hours during the night or as necessary
Adults and children 12 years and over	15 mL or 3 teaspoons at bedtime and every 4 hours during the night or as necessary

Inactive ingredients

Citric Acid, Glycerine, Glycyrrhiza Extract, Purified Water, Sodium Benzoate.

Questions or comments?

(800) 624-9659

***CLAIMS BASED ON TRADITIONAL
HOMEOPATHIC PRACTICE, NOT ACCEPTED
MEDICAL EVIDENCE. NOT FDA EVALUATED.**

Principal Display Panel - Kit Carton

NDC 54973-3381-1

HOMEOPATHIC

Ages

2-12

NATURAL

RELIEF

SINCE 1903

Hyland's

4 Kids

Cold'n Mucus*

Loosens mucus in chest, throat and nose

Day & Night Value Pack

DAYTIME

Mucus & Congestion

Runny Nose

Cough

ALCOHOL FREE

SUGAR FREE

DYE FREE

4 FL. OZ. (118 mL) Daytime

NIGHTTIME

Mucus & Congestion

Occasional Sleeplessness

Runny Nose

Cough

LESS THAN 0.2% ALCOHOL

SUGAR FREE

DYE FREE

4 FL. OZ. (118 mL) Nighttime

8 FL. OZ. (236 mL) TOTAL



4 KIDS COLD AND MUCUS

euphrasia stricta, silicon dioxide, rumex crispus root, anemone pulsatilla, goldenseal, sodium chloride, phosphorus, onion, bryonia alba root, matricaria chamomilla, arabica coffee bean, calcium sulfide and sulfur kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3381
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3381-1	1 in 1 CARTON	08/01/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	118 mL
Part 2	1 BOTTLE, PLASTIC	118 mL

Part 1 of 2

4 KIDS COLD AND MUCUS NIGHTTIME

euphrasia stricta,silicon dioxide, rumex crispus root, anemone pulsatilla, goldenseal, sodium chloride, phosphorus, onion, bryonia alba root, matricaria chamomilla, arabica coffee bean, calcium sulfide and sulfur liquid

Product Information

Item Code (Source)	NDC:54973-3372
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	3 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL
RUMEX CRISPUS ROOT (UNII: 9N1RM2S62C) (RUMEX CRISPUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPUS ROOT	6 [hp_X] in 1 mL
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	6 [hp_X] in 1 mL
EUPHRASIA STRICTA (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	3 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3372-2	1 in 1 CARTON		
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/27/2018	

Part 2 of 2
4 KIDS COMPLETE COLD AND MUCUS bryonia alba root, euphrasia stricta, calcium sulfide, sodium chloride, phosphorus, anemone pulsatilla, rumex crispus root, and silicon dioxide liquid

Product Information	
Item Code (Source)	NDC:54973-3179
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
EUPHRASIA STRICTA (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	6 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL

SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
RUMEX CRISPUS ROOT (UNII: 9N1RM2S62C) (RUMEX CRISPUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPUS ROOT	6 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3179-1	1 in 1 CARTON		
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/01/2018	

Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549198	manufacture(54973-3381) , pack(54973-3381) , label(54973-3381)

Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		117337220	manufacture(54973-3381) , pack(54973-3381) , label(54973-3381)

