

**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
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 Nighttime

Drug Facts

Active ingredients	Purpose
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

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

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.

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.

Drug Facts (continued)

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

PRIMARY PRINCIPAL DISPLAY - 4 FL. OZ. (118 mL) BOTTLE CARTON

NDC 54973-3372-2

HOMEOPATHIC

Ages

2-12

NATURAL

RELIEF

SINCE 1903

Hyland's

4KIDS

Cold'n

Mucus

NIGHTTIME

**Loosens mucus in
chest, throat and nose**

Mucus & Congestion

Occasional Sleeplessness

Runny Nose

Cough

LESS THAN 0.2%ALCOHOL

SUGAR FREE

DYE FREE

4 FL. OZ. (118 mL)





Cold 'n Mucus

NIGHTTIME

NDC 54973-3372-2
HOMEOPATHIC
Ages
2-12



Cold 'n Mucus*

NIGHTTIME

Loosens mucus in chest, throat and nose

- Mucus & Congestion
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- Cough

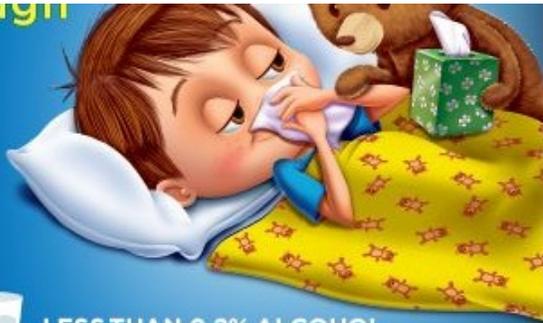


Hyland's 4 Kids Cold 'n Mucus Nighttime provides natural relief to help children with symptoms of cold at night including accumulation of mucus in chest, throat and nose, runny nose, sneezing, and nasal congestion.

Our formulas are safe and always:

Made with natural active ingredients

Cough



LESS THAN 0.2% ALCOHOL
SUGAR FREE
DYE FREE

4 FL. OZ. (118 mL)

Free of artificial colors and flavors

Free of stimulant side effects

Manufactured for:
Hyland's, Inc.
Los Angeles, CA 90061
(800) 624-9659
www.hylands.com

Drug Facts

Active ingredients Purpose

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
Hvdrastis 6X HPUS...cough with mucus. dry. sore throat.

Drug Facts (continued)

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occasional sleeplessness due to mucus in throat
Natrium Muriaticum 6X HPUS...accumulation of mucus in throat, cough up mucus
Phosphorus 30X HPUS.....cough with expectoration of yellow mucus, chest congestion
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Inactive ingredients Citric Acid, Glycerine, Glycyrrhiza Extract, Purified Water, Sodium Benzoate.

Questions or comments?

(800) 624-9659

ALSO TRY THESE OTHER HYLAND'S 4 KIDS PRODUCTS:

Cold 'n Cough

Cold 'n Mucus

Oral Pain Relief

To learn more about our products, visit www.hylands.com

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



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PLEASE RECYCLE

4 KIDS COLD 'N MUCUS NIGHTTIME

Rev. 001

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3372
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	3 [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
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
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
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
RUMEX CRISPUS ROOT (UNII: 9N1RM2S62C) (RUMEX CRISPUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPUS ROOT	6 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3372-2	1 in 1 CARTON	06/27/2018	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3372-1	1 in 1 CARTON	08/01/2018	
2		148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:54973-3372-3	5 mL in 1 PACKET; Type 0: Not a Combination Product	06/27/2018	12/15/2021

Marketing Information

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

Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549198	pack(54973-3372) , label(54973-3372) , manufacture(54973-3372)

Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		117337220	manufacture(54973-3372) , pack(54973-3372) , label(54973-3372)

Revised: 11/2022

Hyland's Inc.