

4KIDS COLD N MUCUS NIGHTTIME- onion, bryonia alba root, matricaria recutita, arabica coffee bean, euphrasia stricta, calcium sulfide, goldenseal, sodium chloride, strychnos nuxvomica seed, phosphorus, anemone pulsatilla, rumex crispus root, silicon dioxide, and sulfur liquid

Hyland's

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.

4Kids 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
Nux Vomica 6X HPUS (0.000016% Alkaloids, calculated)	tired, difficulty falling asleep, frequent waking
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 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 high fever (101°F)
- Cough tends to recur or is accompanied by 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 preprinted tamper band is broken or missing.

Drug Facts (continued)

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

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.

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 54973-3250-1

HOMEOPATHIC

Natural

Relief

Ages

2-12

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

SAFE &

EFFECTIVE

4 FL. OZ. (118 mL)



Official Homeopathic Pharmacopoeia 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 high fever (101°F)
 ■ Cough tends to recur or is accompanied by 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 band is broken or missing.

Para más información en español visite: www.mHylands.com
 DATOS DEL MEDICAMENTO EN EL INTERIOR DE LA CAJA.

ALSO TRY THESE OTHER HYLAND'S 4 KIDS PRODUCTS:
 Cold 'n Cough
 Cold 'n Mucus
 Complete Allergy

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

*The uses for our products are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Loosens mucus in chest, throat and nose
 Afloja mucosidad en el pecho, la garganta y la nariz *

Mucus & Congestion
 Mucosidad y congestión
Occasional Sleeplessness
 Insomnio ocasional
Runny Nose
 Goteo nasal
Cough
 Tos

LESS THAN 0.2% ALCOHOL
 SUGAR FREE Sin azúcar
 DYE FREE Sin tintas

SAFE & EFFECTIVE
 Seguro y eficaz

4 FL. OZ. (118 mL)

sneezing, and nasal congestion.

Our formulas are always:
 Safe & effective
 Made with natural active ingredients
 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

Rev. 003

3 54973 32501 2
 PLEASE RECYCLE
 4 KIDS COLD 'N MUCUS NIGHTTIME

4KIDS COLD N MUCUS NIGHTTIME

onion, bryonia alba root, matricaria recutita, arabica coffee bean, euphrasia stricta, calcium sulfide, goldenseal, sodium chloride, strychnos nux-vomica seed, phosphorus, anemone pulsatilla, rumex crispus root, silicon dioxide, and sulfur liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3250
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 RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	3 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	3 [hp_X] in 1 mL
EUPHRASIA STRICTA (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL

GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	6 [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
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
LICORICE (UNII: 61ZBX54883)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3250-1	1 in 1 CARTON	04/29/2016	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3250-2	5 mL in 1 POUCH; Type 0: Not a Combination Product	11/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/29/2016	

Labeler - Hyland's (028570695)

Establishment

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		008316655	manufacture(54973-3250) , pack(54973-3250)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Nexgen Pharma, Inc.		079424083	manufacture(54973-3250) , pack(54973-3250)
---------------------	--	-----------	--

Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		117337220	pack(54973-3250)

Revised: 12/2017

Hyland's