

**4 KIDS COLD AND COUGH NIGHTTIME- onion, calcium sulfide, sodium chloride, anemone pulsatilla, arabica coffee bean, matricaria chamomilla, sulfur, phosphorus and goldenseal 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.*

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**4 Kids Cold'n Cough Nighttime**

**Drug Facts**

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<b>Active ingredients</b>	<b>Purpose</b>
Allium Cepa 6X HPUS	watery/runny nose, cold, hacking cough, painful throat
Chamomilla 6X HPUS	sensitive, irritable, fussy, nocturnal occasional sleeplessness
Coffea Cruda 6X HPUS	occasional sleeplessness, restlessness
Hepar Sulph Calc 12X HPUS	cold, sneezing
Hydrastis 6X HPUS	rattling/tickling cough, sinus congestion, dry/raw/sore throat
Natrum Muriaticum 6X HPUS	dry cough, sore throat
Phosphorus 12X HPUS	hoarse/dry cough, nasal congestion, chest congestion
Pulsatilla 6X HPUS	moist cough, cold, post nasal drip
Sulphur 12X HPUS	chest congestion, nasal congestion, sneezing, runny nose

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

**Uses**

- Temporarily relieves symptoms of common cold in children at night, including:
- cough ■ runny nose ■ post nasal drip
- sneezing ■ nasal or chest congestion
- sore throat ■ occasional sleeplessness

**Warnings**

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Ask a doctor before use if you have:** □ persistent or chronic cough such as

smoking, asthma, chronic bronchitis or emphysema. A persistent cough may be a sign of a serious condition. ☐ cough that is accompanied by excessive phlegm (mucus).

**Stop use and ask a doctor if:** ☐ symptoms persist for more than 7 days or worsen. ☐ inflammation, fever or infection is present or develops. ☐ cough tends to recur or is accompanied by a fever, rash or persistent headache.

**If pregnant or breastfeeding,** ask a health professional before use.

**Keep out of reach of children.**

### ***Directions***

☐ Use as directed. ☐ Do not refrigerate. ☐ Shake well before using. ☐ Measure only with the dosing cup provided. ☐ Do not use dosing cup with other products. ☐ On dosing cup, mL = milliliter.

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Children 2 years to under 6 years	5 mL at bedtime and every 4 hours during the night until relieved.
Children 6 years to under 12 years	10 mL at bedtime and every 4 hours during the night until relieved.
Adults and children 12 years and over	15 mL at bedtime and every 4 hours during the night until relieved.

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### ***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.**

DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING.

### **PACKAGE LABEL-PRINCIPAL DISPLAY PANEL**

**Hyland's**

NATURALS™

•Kids•

**Cold &**

**Cough\***

NIGHTTIME

NO ALCOHOL, SUGAR,



## 4 KIDS COLD AND COUGH NIGHTTIME

onion, calcium sulfide, sodium chloride, anemone pulsatilla, arabica coffee bean, matricaria chamomilla, sulfur, phosphorus and goldenseal liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-3375
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ONION</b> (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
<b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
<b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
<b>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_X] in 1 mL
<b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
<b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 1 mL
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3375-1	1 in 1 CARTON	07/01/2018	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3375-2	5 mL in 1 PACKET; Type 0: Not a Combination Product	07/01/2018	12/15/2021
3	NDC:54973-3375-3	1 in 1 CARTON	07/01/2018	

3	148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/01/2018	

**Labeler** - Hyland's (028570695)

**Registrant** - Standard Homeopathic Company (Hyland's) (008316655)

**Establishment**

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		080253323	manufacture(54973-3375) , pack(54973-3375) , label(54973-3375)

**Establishment**

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		876754375	manufacture(54973-3375) , pack(54973-3375) , label(54973-3375)

Revised: 12/2021

Hyland's