

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

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**Hyland's Kids Cold 'n Cough Day & Night Combo Pack Grape Flavor**

Relieves congestion, runny nose, sore throat, sneezing, cough, post nasal drip and occasional sleeplessness

**DAYTIME**

***Drug Facts***

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<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Allium Cepa 6X HPUS	watery/runny nose, cold, hacking cough, painful throat
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, including:

- runny nose ■ sore throat ■ sneezing
- cough ■ post nasal drip
- nasal or chest congestion

***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 up to 6 times per day (every 4 hours).
Children 6 years to under 12 years	10 mL up to 6 times per day (every 4 hours).
Adults and children 12 years and over	15 mL up to 6 times per day (every 4 hours).

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### ***Inactive ingredients***

Citric Acid, Glycerine, Glycyrrhiza Extract, Natural Grape Flavor, Purified Water, Sodium Benzoate.

## **NIGHTTIME**

### ***Drug Facts***

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<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Allium Cepa 6X HPUS	watery/runny nose, cold, hacking cough, painful throat
Chamomilla 6X HPUS	occasional sleeplessness
Coffea Cruda 6X HPUS	occasional sleeplessness
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, Natural Grape Flavor, Purified Water, Sodium Benzoate.

## Questions?

(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 - KIT CARTON**

**Hyland's**

**•KIDS•**

**Cold & Cough**

COMBO PACK

NO ALCOHOL, SUGAR,

PARABENS or DYES

**DAYTIME**

Congestion

Runny Nose

Sore Throat

Cough

Post Nasal

Drip

**NIGHTTIME**

Sleeplessness

Congestion

Runny Nose

Sore Throat

Cough

Post Nasal

Drip

**2-12 YEARS**

**NATURAL**

**GRAPE FLAVOR**

**TWO - 4 FL. OZ. (118 mL) Bottles (1 Day, 1 Night) | TOTAL 8 FL. OZ. (236 ML)**

HOMEOPATHIC

**NO  
COAT**

Open for  
more playtime!

Keep those pesky  
cold & cough symptoms  
under control 'round  
the clock in one  
convenient bundle.\*

Non-drowsy formula  
for symptom relief  
during the day.\* Safe,  
relaxing formula for  
a restful night.\*

Safe & Gentle  
Natural Active Ingredients  
Kid Approved Taste

**NO  
COAT**

**Hyland's  
kids**

**Cold & Cough<sup>®</sup>**  
COMBO PACK

DAYTIME NIGHTTIME

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**Hyland's  
kids**

**Cold & Cough<sup>®</sup>**  
COMBO PACK

NO ALCOHOL, SUGAR, PARABENS OR DYES

**DAYTIME**

Congestion\*  
Runny Nose\*  
Sore Throat\*  
Cough\*  
Post Nasal  
Drip\*

**NIGHTTIME**

Sleeplessness\*  
Congestion\*  
Runny Nose\*  
Sore Throat\*  
Cough\*  
Post Nasal  
Drip\*

2-12 YEARS

NATURAL GRAPE FLAVOR

TWO - 4 FL. OZ. (118 mL) Bottles (1 Day, 1 Night)

HOMEOPATHIC

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**A kinder  
way to care  
for kids.**

Kindness is our north star.  
Kindness to our bodies,  
hearts, and minds.  
That's why our remedies  
are made with natural,  
gentle active ingredients.  
For all those not-so-feel-good  
moments, we're here to help.

REV001

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

DAYTIME	NIGHTTIME
<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b></p> <p>4oz. Grape 6X HPUS</p> <p>Hepar Sulph. Carb. 12X HPUS</p> <p>Hydrastis 6X HPUS</p> <p>Natural Mentholum 6X HPUS</p> <p>Phosphorus 12X HPUS</p> <p>4oz. Grape 6X HPUS</p> <p>Hepar Sulph. Carb. 12X HPUS</p> <p>Hydrastis 6X HPUS</p> <p>Natural Mentholum 6X HPUS</p> <p>Phosphorus 12X HPUS</p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b></p> <p>4oz. Grape 6X HPUS</p> <p>Chamom. 6X HPUS</p> <p>Coffea Cruda 6X HPUS</p> <p>Hepar Sulph. Carb. 12X HPUS</p> <p>Hydrastis 6X HPUS</p> <p>Natural Mentholum 6X HPUS</p> <p>Phosphorus 12X HPUS</p> <p>4oz. Grape 6X HPUS</p> <p>Hepar Sulph. Carb. 12X HPUS</p> <p>Hydrastis 6X HPUS</p> <p>Natural Mentholum 6X HPUS</p> <p>Phosphorus 12X HPUS</p>
<p><b>Purpose*</b></p> <p>wet/dry/runny nose, cold, hacking cough, sore throat</p> <p>cold, sneezing</p> <p>wet/dry/runny nose, cold, runny congestion, dry/irritated throat</p> <p>dry cough, sore throat</p> <p>nearby/irritating cough</p> <p>nasal congestion, chest congestion</p> <p>sore throat, cold, post nasal drip</p> <p>chest congestion, nasal congestion, sneezing, runny nose</p>	<p><b>Purpose*</b></p> <p>wet/dry/runny nose, cold, hacking cough, sore throat</p> <p>occasional sleeplessness</p> <p>occasional sleeplessness</p> <p>cold, sneezing</p> <p>wet/dry/runny nose, cold, runny congestion, dry/irritated throat</p> <p>dry cough, sore throat</p> <p>nearby/irritating cough</p> <p>nasal congestion, chest congestion</p> <p>nasal congestion, chest congestion</p> <p>nasal congestion, chest congestion</p> <p>nasal congestion, chest congestion</p> <p>nasal congestion, chest congestion</p>
<p><b>Uses*</b></p> <p>Helps temporarily relieve symptoms of common cold in children, including:</p> <p>runny nose</p> <p>sore throat</p> <p>sneezing</p> <p>cough</p> <p>post nasal drip</p> <p>nasal or chest congestion</p>	<p><b>Uses*</b></p> <p>Helps temporarily relieve symptoms of common cold in children at night, including:</p> <p>cough</p> <p>runny nose</p> <p>post nasal drip</p> <p>sneezing</p> <p>sore throat</p> <p>nasal or chest congestion</p> <p>occasional sleeplessness</p>
<p><b>Warnings</b></p> <p><b>Severe throat warning:</b> 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.</p> <p><b>Ask a doctor before use if you have:</b> persistent or chronic cough such as smoking, asthma, chronic bronchitis or emphysema. A persistent cough may be a sign of a serious condition.</p> <p><b>Stop use and ask a doctor if:</b> 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.</p> <p><b>If pregnant or breastfeeding,</b> ask a health professional before use. Keep out of reach of children.</p>	<p><b>Warnings</b></p> <p><b>Severe throat warning:</b> 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.</p> <p><b>Ask a doctor before use if you have:</b> persistent or chronic cough such as smoking, asthma, chronic bronchitis or emphysema. A persistent cough may be a sign of a serious condition.</p> <p><b>Stop use and ask a doctor if:</b> 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.</p> <p><b>If pregnant or breastfeeding,</b> ask a health professional before use. Keep out of reach of children.</p>
<p><b>Directions</b></p> <p>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. = 1/2 fl. oz.</p> <p>Children 2 years to under 4 years 5 mL, up to 6 times per day every 4 hours.</p> <p>Children 4 years to under 12 years 10 mL, up to 6 times per day every 4 hours.</p> <p>Adults and children 12 years and over 15 mL, up to 6 times per day every 4 hours.</p>	<p><b>Directions</b></p> <p>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. = 1/2 fl. oz.</p> <p>Children 2 years to under 4 years 5 mL, at bedtime and every 4 hours during the night until relieved.</p> <p>Children 4 years to under 12 years 10 mL, at bedtime and every 4 hours during the night until relieved.</p> <p>Adults and children 12 years and over 15 mL, at bedtime and every 4 hours during the night until relieved.</p>
<p><b>Inactive ingredients</b> Citric Acid, Glycerine, Erythritol, Extract, Natural Grape Flavor, Purified Water, Sodium Benzoate.</p>	<p><b>Inactive ingredients</b> Citric Acid, Glycerine, Erythritol, Extract, Natural Grape Flavor, Purified Water, Sodium Benzoate.</p>

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

Questions? [www.hylands.com](http://www.hylands.com) or [care@hylands.com](mailto:care@hylands.com)

<b>4 KIDS COLD AND COUGH DAY AND NIGHT GRAPE FLAVOR</b>				
onion, anemone pulsatilla, phosphorus, goldenseal, calcium sulfide, sodium chloride, sulfur, matricaria chamomilla and arabica coffee bean kit				
Product Information				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-3379	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3379-1	1 in 1 CARTON; Type 0: Not a Combination Product	12/01/2018	
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 N COUGH GRAPE FLAVOR

onion, calcium sulfide, goldenseal, sodium chloride, phosphorus, anemone pulsatilla, and sulfur liquid

#### Product Information

**Item Code (Source)** NDC:54973-3243

**Route of Administration** 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>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	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) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
<b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [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>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

#### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3243-1	1 in 1 CARTON		

1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/10/2016	

## Part 2 of 2

### 4 KIDS COLD AND COUGH NIGHTTIME NATURAL GRAPE FLAVOR

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

## Product Information

<b>Item Code (Source)</b>	NDC:54973-3377
<b>Route of Administration</b>	ORAL

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	

GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)

SODIUM BENZOATE (UNII: OJ245FE5EU)

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3377-1	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		11/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/01/2018	

**Labeler** - Hyland's Inc. (008316655)

### Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3379)

### Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc		117337220	manufacture(54973-3379) , pack(54973-3379) , label(54973-3379)

Revised: 4/2025

Hyland's Inc.