

**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.

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

Active ingredients	Purpose
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

"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.

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).

Inactive ingredients

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

NIGHTTIME

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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

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.

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.

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



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 kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-4127
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-4127-1	1 in 1 CARTON; Type 0: Not a Combination Product	06/05/2024	

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
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3243-1	1 in 1 CARTON		
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**NO
COAT**

Open for
more playtime!

Hyland's.
kids
**Cold &
Cough**[®]

DAYTIME

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

Drug Facts

Active ingredients	Purpose*
Album Cepae 6X HPUS	watery/runny nose, cold, hacking cough, sore throat
Hepar Sulph Calc 12X HPUS	cold, sneezing
Hydrastis 6X HPUS	runny/sticky cough, sinus congestion, dry/sore throat
Natrum Muriaticum 6X HPUS	dry cough, sore throat
Phosphorus 12X HPUS	hoarse/dry cough, nasal congestion, chest congestion
Pulsatilla 6X HPUS	runny nose, cold, post-nasal drip
Sulphur 12X HPUS	chest congestion, nasal congestion, sneezing, runny nose

HPUS is the Homeopathic Pharmacopoeia of the United States.

Uses*

- Helps temporarily relieve 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 7 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, or 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 cap provided. Do not use dosing cap with other products. On dosing cap, ml = milliliter.

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).

Inactive ingredients Citric Acid, Glycerine, Glycyrrhizin Extract, Natural Grape Flavor, Purified Water, Sodium Benzoate.

Questions? www.hylands.com or care@hylands.com

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

Pesky cold symptoms can throw kids off their game. Help ease their discomfort with this gentle and effective solution, so your kid can get back to the business of being a happy kid.*

Safe & Gentle

Natural Active Ingredients

Kid Approved Taste

Hyland's.
kids

**Cold &
Cough**[®]

DAYTIME

NO ALCOHOL, SUGAR,
PARABENS or DYES



2-12
YEARS

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



4 FL. OZ. (118 mL) HOMEOPATHIC



Manufactured for: Hyland's, Inc.
PO Box 81067
Los Angeles, CA 90061
www.hylands.com



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.



02728104

REV001

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

Item Code (Source) NDC:54973-3377

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [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) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 1 mL
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	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)	

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		

NO COAT

NO COAT

Open for more snores!

Pesky cold symptoms can keep your kid up at night. Help soothe their discomfort with this gentle and effective solution, so your kid can get back to being a little dreamer.*

Safe & Gentle

Natural Active Ingredients

Kid Approved Taste

REV001

Hyland's kids

Cold & Cough

NIGHTTIME

Hyland's kids

Cold & Cough

NIGHTTIME

NO ALCOHOL, SUGAR, PARABENS or DYES

Sleeplessness*

Congestion*

Runny Nose*

Sore Throat*

Cough*

Post Nasal Drip*

2-12 YEARS

4 FL. OZ. (118 mL) HOMEOPATHIC

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.

02728103

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Manufactured for Hyland's Inc., PG Box 67067, Los Angeles, CA 90061
www.hylands.com

PLEASE RECYCLE

FOR RPE

ORDER # _____
PP INIT. _____
Date _____

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

Drug Facts

Active ingredients	Purpose*
Aconitum Napellus 6X HPUS	watery/runny nose, cold
Chamomilla 6X HPUS	hoarse cough, painful throat
Coltsfoot 6X HPUS	circumcised throat
Coltsfoot 6X HPUS	circumcised throat
Hepar Sulph 6X HPUS	cold, sneezing
Hydrastis 6X HPUS	congested cough, sinus congestion, dry/irritated throat
Natrium Muriaticum 6X HPUS	dry cough, sore throat
Phosphorus 10X HPUS	hoarse/cough
Pulsatilla 6X HPUS	runny nose, chest congestion
Sulphur 10X HPUS	chest cough, cold, post nasal drip
Sulphur 10X HPUS	chest congestion, nasal congestion, sneezing, runny nose

*HPUS is the Homeopathic Pharmacopoeia of the United States.

Uses*

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

Warnings

See throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, hoarseness, 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/sputum.

Stop use and ask a doctor if: symptoms persist for more than 7 days or worsen, if inflammation, fever or infection is present or develops, if 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 use.
- Measure only with the dosing cup provided. Do not use dosing cup with other products. On dosing cup, mL = milliliter.
- 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.

Active ingredients: Citric Acid, Glycerin, Glycyrrhiza Extract, Natural Grape Flavor, Purified Water, Sodium Benzoate.

Directions? www.hylands.com or call 800-445-4454

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

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(54973-4127) , pack(54973-4127)

Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc		117337220	label(54973-4127) , pack(54973-4127)

Revised: 2/2025

Hyland's Inc.