

**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.

4 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

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

NATURALS™

•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:54973-3379

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 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: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

Marketing Start Marketing End

#	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		

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		

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)