

KIDS COLD AND COUGH COMBO PACK- onion, chamomile, arabica coffee bean, calcium sulfide, golden seal, sodium chloride, phosphorus, pulsatilla vulgaris top, sulfur
Hyland's Consumer Health 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 Naturals Kids Cold & Cough Combo Pack Grape Flavor

Sleeplessness, Congestion, Runny Nose, Sore Throat, Cough, Post Nasal Drip

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" 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 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 4 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

Active ingredients

Purpose*

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" 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

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 4 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?

www.hylands.com or care@hylands.com

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

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

Principal Display Panel

Hyland's

NATURALS™

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*

4 - 12 YEARS

NATURAL

GRAPE FLAVOR

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

HOMEOPATHIC

DAYTIME

Drug Facts

Active Ingredients

Purpose*

Warnings

Directions

Inactive Ingredients

NIGHTTIME

Drug Facts

Active Ingredients

Purpose*

Warnings

Directions

Inactive Ingredients

Open for more playtime!

Keep those pesky cold & cough symptoms under control* around 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

Hyland's NATURAL'S kids Cold & Cough COMBO PACK

DAYTIME NIGHTTIME

Hyland's NATURAL'S kids Cold & Cough COMBO PACK

NO ALCOHOL, SUGAR, PARABENS or DYES

DAYTIME	NIGHTTIME
<ul style="list-style-type: none"> Congestion* Runny Nose* Sore Throat* Cough* Post Nasal Drip* 	<ul style="list-style-type: none"> Sleeplessness* Congestion* Runny Nose* Sore Throat* Cough* Post Nasal Drip*

4-12 YEARS

NATURAL GRAPE FLAVOR

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

HOMEOPATHIC

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Manufactured for: Hyland's, Inc. PO Box 61007 Los Angeles, CA 90061 www.hylands.com

PLEASE RECYCLE

REV001

KIDS COLD AND COUGH COMBO PACK

onion, chamomile, arabica coffee bean, calcium sulfide, golden seal, sodium chloride, phosphorus, pulsatilla vulgaris top, sulfur kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-4112
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-4112-1	1 in 1 KIT; Type 0: Not a Combination Product	12/01/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
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Part 1	1 BOTTLE, PLASTIC	118 mL
Part 2	1 BOTTLE, PLASTIC	118 mL

Part 1 of 2

KIDS COLD AND COUGH NIGHTTIME GRAPE FLAVOR

onion, chamomile, arabica coffee bean, calcium sulfide, golden seal, sodium chloride, phosphorus, pulsatilla vulgaris top, sulfur liquid

Product Information

Item Code (Source)	NDC:54973-4111
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	6 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 1 mL
PULSATILLA VULGARIS TOP (UNII: 4F1D271XW0) (PULSATILLA VULGARIS TOP - UNII:4F1D271XW0)	PULSATILLA VULGARIS TOP	6 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KOOR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	

Product Characteristics

Color		Score	
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Shape		Size	
Flavor	GRAPE (Natural Grape Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-4111-1	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		12/01/2022	

Part 2 of 2

KIDS COLD AND COUGH DAYTIME GRAPE FLAVOR

onion, calcium sulfide, golden seal, sodium chloride, phosphorus, pulsatilla vulgaris whole, sulfur liquid

Product Information

Item Code (Source)	NDC:54973-4110
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
PULSATILLA VULGARIS WHOLE (UNII: I76KB35JEV) (PULSATILLA VULGARIS WHOLE - UNII:I76KB35JEV)	PULSATILLA VULGARIS WHOLE	6 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

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

Product Characteristics		
Color		Score
Shape		Size
Flavor	GRAPE (Natural Grape Flavor)	Imprint Code
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-4110-1	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		12/01/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/01/2022	

Labeler - Hyland's Consumer Health Inc. (008316655)

Establishment			
Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-4112) , pack(54973-4112) , label(54973-4112)