

**4 KIDS COLD AND COUGH DAYTIME AND NIGHTTIME- onion, calcium sulfide, sodium chloride, anemone pulsatilla, arabica coffee bean, matricaria chamomilla, sulfur, phosphorus and goldenseal
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 Naturals Kids Cold 'n Cough Combo Pack

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 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, 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 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, 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.

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.

Principal Display Panel - Kids Cold & Cough Daytime Nighttime Combo Pack

Hyland's

NATURALS™

•baby•

Cold & Cough*

COMBO BACK

NO ALCOHOL, SUGAR, PARABENS or DYES

DAYTIME

Congestion*

Runny Nose*

Sore Throat*

Cough*

Post Nasal

Drip*

NIGHTTIME

Sleeplessness*

Congestion*

Runny Nose*

Sore Throat*

Cough*

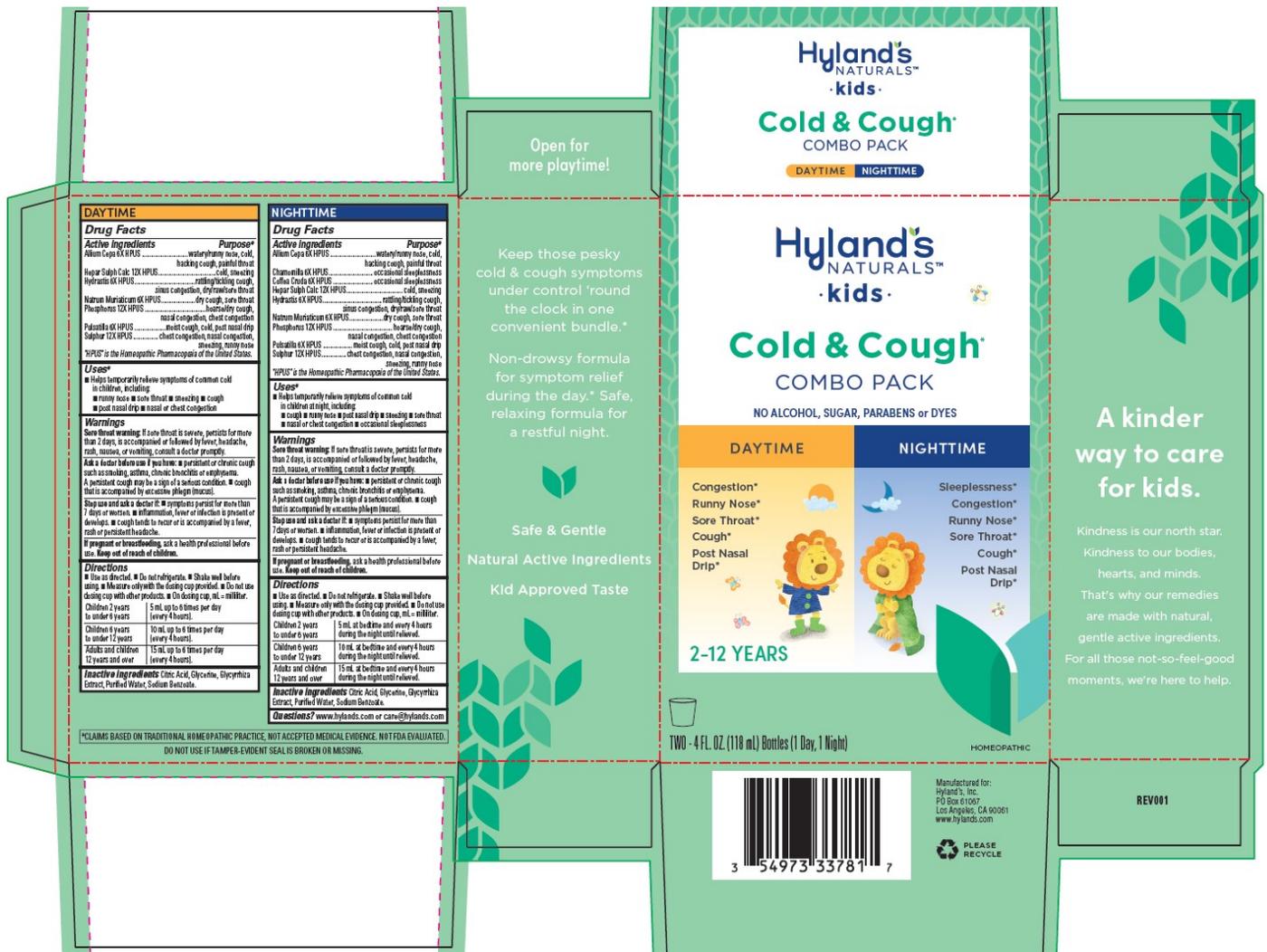
Post Nasal

Drip*

2 - 12 YEARS

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

HOMEOPATHIC



4 KIDS COLD AND COUGH DAYTIME AND NIGHTTIME

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3378

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3378-1	1 in 1 CARTON; Type 0: Not a Combination Product	06/08/2018	

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

COLD AND COUGH 4 KIDS

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

Product Information

Item Code (Source) NDC:54973-3075

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3075-1	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		08/01/2008	

homeopathic

06/01/2006

Part 2 of 2**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

Item Code (Source) NDC:54973-3375

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [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)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:54973			

1	NDC:54973-3375-1	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		07/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/08/2018	

Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3378) , pack(54973-3378) , label(54973-3378)

Revised: 9/2023

Hyland's Inc.