

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*

Alum. Caps. 6X HPUS watery/runny nose, cold, hacking cough, painful throat

Hepar Sulph. Carb. 12X HPUS cold, sneezing

Hydrastis 6X HPUS rattling/bubbling cough

Natrum Muraticum 6X HPUS almost complete, dryness/hoarse throat

Phosphorus 12X HPUS dry cough, sore throat

Pulsatilla 6X HPUS nasal congestion, chest congestion

Sulphur 12X 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, hoarseness, or vomiting, consult a doctor promptly.

Ask a doctor before use if you have a persistent or chronic cough such as smoking, asthma, chronic bronchitis or emphysema.

A persistent cough may be a sign of a serious condition. A cough that is accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if symptoms persist for more than 7 days or worsen, an inflammation, fever or infection is present or develops, a 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 4 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, Citricolite, 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.

NIGHTTIME

Drug Facts

Active Ingredients Purpose*

Alum. Caps. 6X HPUS watery/runny nose, cold, hacking cough, painful throat

Chamomilla 6X HPUS occasional sleeplessness

Colloidal Sulphur 6X HPUS occasional sleeplessness

Hepar Sulph. Carb. 12X HPUS cold, sneezing

Hydrastis 6X HPUS rattling/bubbling cough

Natrum Muraticum 6X HPUS almost complete, dryness/hoarse throat

Phosphorus 12X HPUS dry cough, sore throat

Pulsatilla 6X HPUS hoarse/baby cough

Sulphur 12X HPUS nasal congestion, chest congestion

Sulphur 12X 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, hoarseness, or vomiting, consult a doctor promptly.

Ask a doctor before use if you have a persistent or chronic cough such as smoking, asthma, chronic bronchitis or emphysema.

A persistent cough may be a sign of a serious condition. A cough that is accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if symptoms persist for more than 7 days or worsen, an inflammation, fever or infection is present or develops, a 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 12 years | 5 mL, up to 4 times per day (every 4 hours). |
| Children 12 years and over | 10 mL, at bedtime and every 4 hours during the night until relieved. |

Inactive Ingredients Citric Acid, Citricolite, Glycyrrhiza Extract, Natural Grape Flavor, Purified Water, Sodium Benzoate.

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

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

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

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

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

PLEASE RECYCLE

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.

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 |
|---------------------|----------------|---------------------------|----------------|

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 |
|--------|------------------|------------------------|
| | | |

| | | |
|---------------|-------------------|--------|
| 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: 059QF0KO0R) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) | |

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:54973-4111-1 | 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) |