

**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  
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.*

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**Hyland's Naturals Kids Cold & Cough Nighttime Natural Grape Flavor**

Relieves congestion, runny nose, sore throat, sneezing, cough, post nasal drip and occasional sleeplessness

***Drug Facts***

***Active ingredients***

Allium Cepa 6X HPUS .....watery/runny nose, cold, hacking cough, painful throat

Chamomilla 6X HPUS ..... sensitive, irritable, fussy, nocturnal occasional sleeplessness

Coffea Cruda 6X HPUS.....occasional sleeplessness, restlessness

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

***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.

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|                                       |   |
|---------------------------------------|---|
| 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. |

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### ***Inactive ingredients***

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

### ***Questions?***

[www.hylands.com](http://www.hylands.com) or [care@hylands.com](mailto: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.

### ***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

Hyland's

NATURALS™

•Kids•

Cold & Cough

NIGHTTIME

NO ALCOHOL, SUGAR,

PARABENS or DYES\*

Sleeplessness

Congestion

Runny Nose

Sore Throat

Cough

Post Nasal

Drip

2-12

YEARS

NATURAL

GRAPE FLAVOR

4 FL. OZ. (118 mL)

HOMEOPATHIC

Open for  
more snores!

**Drug Facts**

| Active ingredients        | Purpose   |
|---------------------------|---|
| Alum 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         | stiffening/hacking cough, sinus congestion, dry/sore throat |
| Natron Muriacicum 6X HPUS | dry cough, sore throat                                      |
| Phosphorus 12X HPUS       | hours/whole day cough, nasal congestion, chest irritation   |
| 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 at night, including:  
 ■ cough ■ runny nose ■ postnasal 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 leads to ruc 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 nighttime relieved.  |
| Children 6 years to under 12 years    | 10 mL at bedtime and every 4 hours during the nighttime relieved. |
| Adults and children 12 years and over | 15 mL at bedtime and every 4 hours during the nighttime 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.

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

Hyland's  
NATURALS™  
·kids·  
**Cold & Cough**  
NIGHTTIME

Hyland's  
NATURALS™  
·kids·  
**Cold & Cough**  
NIGHTTIME

NO ALCOHOL, SUGAR, PARABENS or DYES



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

2-12  
YEARS

NATURAL GRAPE FLAVOR  
 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 all our remedies are made with natural, gentle active ingredients. For all those not-so-feel-good moments, we're here to help.

REV001



Manufactured for: Hyland's, Inc.  
 PO Box 61067, Los Angeles, CA 90061  
 www.hylands.com



**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.**

\*CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED.  
 Do not use if tamper-evident seal is broken or missing. Questions? [www.hylands.com](http://www.hylands.com) or [care@hylands.com](mailto:care@hylands.com)

**Hyland's kids**  
NATURALS™

## Cold & Cough\*

**NIGHTTIME**

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



**2-12 YEARS**

NATURAL GRAPE FLAVOR

**4 FL. OZ. (118 mL)**

HOMEOPATHIC

PEEL FOR DIRECTIONS & MORE INFORMATION

**Directions:**

- Use as directed.
- Shake well before using.
- Do not use dosing cup with other products.
- Do not refrigerate.
- Measure only with the dosing cup provided.
- 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:** Allium Cepa 6X HPUS, Chamomilla 6X HPUS, Coffea Cruda 6X HPUS, Hepar Sulph Calc 12X HPUS, Hydrastis 6X HPUS, Natrum Muriaticum 6X HPUS, Phosphorus 12X HPUS, Pulsatilla 6X HPUS, Sulphur 12X HPUS. **Inactive ingredients:** Citric Acid, Glycerine, Glycyrrhiza Extract, Natural Grape Flavor, Purified Water, Sodium Benzoate.

**Manufactured for: Hyland's, Inc., PO Box 61067, Los Angeles, CA 90061**  
[www.hylands.com](http://www.hylands.com) REV001 NDC 54973-3377-1

**NDC 54973-3377-3 5 FL. OZ. (148 mL)**

Open for more snozes!

25% MORE BONUS PACK

Peaky 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**

Kindness is our north star, kindness to our bodies, hearts, and minds. That's why all our remedies are made with natural, gentle active ingredients. For all those not-so-feel-good moments, we're here to help.

**Hyland's**  
**NATURALS™**  
**· Kids ·**  
**Cold & Cough**  
**NIGHTTIME**

**2-12 YEARS**  
 NO ALCOHOL, SUGAR, PARABENS or DYES  
 Sleeplessness  
 Congestion  
 Runny Nose  
 Sore Throat  
 Cough  
 Post Nasal Drip

**Hyland's**  
**NATURALS™**  
**· Kids ·**  
**Cold & Cough**  
**NIGHTTIME**

**5 FL. OZ. (149 mL)**  
 HOMEOPATHIC

REV001

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Hyland's  
 Naturals, Inc.  
 Los Angeles, CA 90061  
 www.hylands.com

PLEASE RECYCLE

**Hyland's · kids**  
**NATURALS™**  
**Cold & Cough\***  
**NIGHTTIME**

Sleeplessness  
 Congestion  
 Runny Nose  
 Sore Throat  
 Cough  
 Post Nasal Drip

**2-12 YEARS**

**NATURAL GRAPE FLAVOR**  
**5 FL. OZ. (149 mL)**  
**HOMEOPATHIC**

**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.

**Active ingredients:** Allium Cepa 6X HPUS, Chamomilla 6X HPUS, Coffea Cruda 6X HPUS, Hepar Sulph Calc 12X HPUS, Hydrastis 6X HPUS, Natrum Muriaticum 6X HPUS, Phosphorus 12X HPUS, Pulsatilla 6X HPUS, Sulphur 12X HPUS. **Inactive ingredients:** Citric Acid, Glycerine, Glycyrrhiza Extract, Natural Grape Flavor, Purified Water, Sodium Benzoate.

**Manufactured for: Hyland's, Inc., PO Box 61067, Los Angeles, CA 90061 REV001 NDC 54973-3377-3**

\*CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED. DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING. QUESTIONS? WWW.HYLANDS.COM OR CARE@HYLANDS.COM

**Drug Facts**

**Active ingredients**  
 Allium cepa 6X HPUS  
 Chamomilla 6X HPUS  
 Coffea cruda 6X HPUS  
 Hepar sulph  
 Hydrastis 6X HPUS  
 Natrum muriaticum 6X HPUS  
 Phosphorus 12X HPUS  
 Pulsatilla 6X HPUS  
 Sulphur 12X HPUS

**Purpose**  
 Temporary relief of symptoms of common cold in children at night, including:  
 ■ cough  
 ■ chest congestion  
 ■ nasal congestion  
 ■ post nasal drip  
 ■ runny nose  
 ■ sore throat  
 ■ sneezing  
 ■ 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.**

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**Contains grape flavor.**

**Keep out of reach of children.**

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**Hyland's**  
**NATURALS™**  
**· Kids ·**  
**Cold & Cough**  
**NIGHTTIME**

**5 FL. OZ. (149 mL)**  
 HOMEOPATHIC

**PLEASE RECYCLE**

# 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

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:54973-3377 |
| <b>Route of Administration</b> | ORAL           |                           |                |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength     | Strength             |
|---|-----------------------|----------------------|
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)                | SODIUM CHLORIDE       | 6 [hp_X]<br>in 1 mL  |
| <b>ONION</b> (UNII: 492225Q21H) (ONION - UNII:492225Q21H)                                 | ONION                 | 6 [hp_X]<br>in 1 mL  |
| <b>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ) | MATRICARIA CHAMOMILLA | 6 [hp_X]<br>in 1 mL  |
| <b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)     | ARABICA COFFEE BEAN   | 6 [hp_X]<br>in 1 mL  |
| <b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)             | CALCIUM SULFIDE       | 12 [hp_X]<br>in 1 mL |
| <b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)                       | GOLDENSEAL            | 6 [hp_X]<br>in 1 mL  |
| <b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)                       | PHOSPHORUS            | 12 [hp_X]<br>in 1 mL |
| <b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)       | ANEMONE PULSATILLA    | 6 [hp_X]<br>in 1 mL  |
| <b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)                               | SULFUR                | 12 [hp_X]<br>in 1 mL |

## Inactive Ingredients

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

## Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    |       | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   | GRAPE | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

## Packaging

| # | Item Code | Package Description | Marketing Start | Marketing End |
|---|-----------|---------------------|-----------------|---------------|
|---|-----------|---------------------|-----------------|---------------|

| # | Item Code        | Package Description  | Date       | Date       |
|---|------------------|--|------------|------------|
| 1 | NDC:54973-3377-1 | 1 in 1 CARTON  | 11/01/2018 |            |
| 1 |                  | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |            |            |
| 2 | NDC:54973-3377-2 | 5 mL in 1 PACKET; Type 0: Not a Combination Product            | 11/01/2018 | 12/15/2021 |
| 3 | NDC:54973-3377-3 | 1 in 1 CARTON  | 11/01/2018 |            |
| 3 |                  | 148 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           |                    |

**Labeler** - Hyland's Inc. (008316655)

## Establishment

| Name          | Address | ID/FEI    | Business Operations  |
|---------------|---------|-----------|--|
| Hyland's Inc. |         | 008316655 | manufacture(54973-3377) , pack(54973-3377) , label(54973-3377) |

Revised: 6/2023

Hyland's Inc.