

**4 KIDS COLD N COUGH DAY AND NIGHT VALUE PACK- onion, calcium sulfide, sodium chloride, phosphorus, pulsatilla vulgaris, sulfur, goldenseal, strychnos nux-vomica seed, coffee bean, and chamomile Hylands 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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**4 Kids Cold 'n Cough Day & Night Value Pack**

**DAYTIME  
Drug Facts**

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<b>Active ingredients</b>	<b>Purpose</b>
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, nasal congestion
Sulphur 12X HPUS	chest congestion, nasal congestion, sneezing, runny nose

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*"HPUS" indicates the active ingredients are in the official Homeopathic Pharmacopœia of the United States.*

**Uses**

Temporarily relieves the symptoms of the common cold including nasal and chest congestion, runny nose, sore throat, sneezing, and cough.

**Warnings**

**As with any drug, ask a doctor before use if pregnant or breast-feeding. Consult a physician if:**

- Symptoms persist for more than 7 days or worsen
- Inflammation, fever or infection develops
- Symptoms are accompanied by high fever (101°F)
- Cough tends to recur or is accompanied by high fever, rash or persistent headache

**Keep this and all medications out of the reach of children.** In case of accidental overdose, contact a medical professional or a poison control center immediately.

**Do not use this product for** persistent or chronic cough such as asthma, smoking or emphysema or if cough is accompanied by excessive mucus, unless directed by a licensed health care professional.

**A persistent cough may be a sign of a serious condition.**

### **Sore throat warning**

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.

**Do not use if imprinted tamper band is broken or missing.**

**In case of emergency,** contact a medical professional or Poison Control Center immediately. Hyland's may also be contacted for emergency information about our products 24 hours a day, 7 days per week at (800) 624-9659.

### **Drug Facts (continued)**

#### **Directions**

- Measure only with the dosing cup provided
- Do not use dosing cup with other products
- On dosing cup, tsp = teaspoon

Children 2 years to under 6 years	5 mL or 1 teaspoon up to 6 times per day (every 4 hours)
Children 6 years to under 12 years	10 mL or 2 teaspoons up to 6 times per day (every 4 hours)
Adults and children 12 years and over	15 mL or 3 teaspoons up to 6 times per day (every 4 hours)

#### **Inactive ingredients**

Citric Acid USP, Glycyrrhiza Extract, Purified Water USP, Sodium Benzoate N.F., Vegetable Glycerine USP.

### **NIGHTTIME**

#### **Drug Facts**

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#### **Active ingredients**

Allium Cepa 6X HPUS

Chamomilla 6X HPUS

Coffea Cruda 6X HPUS

Hepar Sulph Calc 12X HPUS

Hydrastis 6X HPUS

Natrium Muriaticum 6X

#### **Purpose**

watery, runny nose, cold, hacking cough, painful throat

sensitive, irritable, fussy, nocturnal occasional sleeplessness

occasional sleeplessness, restlessness

cold, sneezing

rattling/tickling cough, sinus congestion, dry/raw/sore throat

Natural Ingredients of HPUS	dry cough, sore throat
Nux Vomica 6X HPUS	tired, difficulty falling asleep, frequent waking
Phosphorus 12X HPUS	hoarse/dry cough, nasal congestion, chest congestion
Pulsatilla 6X HPUS	moist cough, cold, nasal congestion
Sulphur 12X HPUS	chest congestion, nasal congestion, sneezing, runny nose

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*"HPUS" indicates the active ingredients are in the official Homeopathic Pharmacopœia of the United States*

## Uses

Temporarily relieves the symptoms of the common cold including cough, runny nose, sneezing, nasal and chest congestion, and sore throat with occasional sleeplessness.

## Warnings

**As with any drug, ask a doctor before use if pregnant or breast-feeding.**

**Consult a physician if:**

- Symptoms persist for more than 7 days or worsen
- Inflammation, fever or infection develops
- Symptoms are accompanied by high fever (101°F)
- Cough tends to recur or is accompanied by high fever, rash or persistent headache

**Keep this and all medications out of the reach of children.** In case of accidental overdose, contact a medical professional or a poison control center immediately.

**Do not use this product for** persistent or chronic cough such as asthma, smoking or emphysema or if cough is accompanied by excessive mucus, unless directed by a licensed health care professional.

**A persistent cough may be a sign of a serious condition.**

## Sore throat warning

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.

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**In case of emergency,** contact a medical professional or Poison Control Center immediately. Hyland's may also be contacted for emergency information about our products 24 hours a day, 7 days per week at (800) 624-9659.

## Directions

- Measure only with the dosing cup provided
- Do not use dosing cup with other products
- On dosing cup, tsp = teaspoon

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Children 2 years to under 5 mL or 1 teaspoon at bedtime and every 4 hours during the

6 years	night or as necessary
Children 6 years to under 12 years	10 mL or 2 teaspoons at bedtime and every 4 hours during the night or as necessary
Adults and children 12 years and over	15 mL or 3 teaspoons at bedtime and every 4 hours during the night or as necessary

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### ***Inactive ingredients***

Citric Acid, Glycerine, Glycyrrhiza Extract, Purified Water, Sodium Benzoate.

### ***Questions or comments?***

**(800) 624-9659**

## **PRINCIPAL DISPLAY PANEL - Kit Carton**

### **Natural Relief**

NDC 54973-3177-1

**HOMEOPATHIC\***

### **Ages 2-12**

SINCE 1903

**Hyland's®**

### **4 Kids**

### **Cold 'n Cough\***

### **Day & Night Value Pack**

### **DAYTIME**

Nasal Congestion

Runny Nose

Sore Throat

Sneezing

Cough

ALCOHOL FREE

SUGAR FREE

DYE FREE

4 FL. OZ. (118 mL) Daytime

### **NIGHTTIME**

Chest Congestion

Occasional Sleeplessness

Runny Nose

Sore Throat

Sneezing

Cough

ALCOHOL FREE

SUGAR FREE

DYE FREE

4 FL. OZ. (118 mL) Nighttime

**8 FL. OZ. (236 mL) TOTAL**





### Runny Nose

*Goteo nasal*

### Sore Throat

*Dolor de garganta*

### Sneezing

*Estornudos*

### Cough

*Tos*



**ALCOHOL FREE**  
**SUGAR FREE** *Sin azúcar*  
**DYE FREE** *Sin tintas*

4 FL. OZ. (118 mL) Daytime

### Occasional Sleeplessness

*Insomnio Ocasional*

### Runny Nose

*Goteo nasal*

### Sore Throat

*Dolor de garganta*

### Sneezing

*Estornudos*

### Cough

*Tos*



**ALCOHOL FREE**  
**SUGAR FREE** *Sin azúcar*  
**DYE FREE** *Sin tintas*

4 FL. OZ. (118 mL) Nighttime

8 FL. OZ. (236 mL) TOTAL

Free of artificial colors and flavors

Free of stimulant side effects

Manufactured for:  
Hyland's, Inc.  
Los Angeles, CA 90061  
(800) 624-9659  
www.hylands.com

\* Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

#### 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, nasal congestion

Sulphur 12X HPUS.....chest congestion, nasal congestion, sneezing, runny nose

"HPUS" indicates the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

**Uses** Temporarily relieves the symptoms of the common cold including nasal and chest congestion, runny nose, sore throat, sneezing, and cough.

##### Warnings

As with any drug, ask a doctor before use if pregnant or breast-feeding. Consult a physician if:  
■ Symptoms persist for more than 7 days or worsen

##### Drug Facts (continued)

##### Directions

- Measure only with the dosing cup provided
- Do not use dosing cup with other products
- On dosing cup: mL = milliliter, tsp = teaspoon

Children 2 years to under 6 years | 5 mL or 1 teaspoon up to 6 times per day (every 4 hours)

Children 6 years to under 12 years | 10 mL or 2 teaspoons up to 6 times per day (every 4 hours)

Adults and children 12 years and over | 15 mL or 3 teaspoons 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 ..... sensitive, irritable, fussy, nocturnal occasional sleeplessness

##### Drug Facts (continued)

- Inflammation, fever or infection develops
- Symptoms are accompanied by high fever (101°F)
- Cough tends to recur or is accompanied by high fever, rash or persistent headache

**Keep this and all medications out of the reach of children.** In case of accidental overdose, contact a medical professional or Poison Control Center immediately.

**Do not use this product** for persistent or chronic cough such as asthma, smoking or emphysema or if cough is accompanied by excessive mucus, unless directed by a licensed medical professional.

**A persistent cough may be a sign of a serious condition.**

**Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.

**Do not use if imprinted tamper band is broken or missing.**

**In case of emergency,** contact a medical professional or Poison Control Center immediately. Hyland's may also be contacted for emergency information about our products 24 hours a day.

- Inflammation, fever or infection develops
- Symptoms are accompanied by high fever (101°F)
- Cough tends to recur or is accompanied by high fever, rash or persistent headache

**Keep this and all medications out of the reach of children.** In case of accidental overdose, contact a medical professional or Poison Control Center immediately.

**Do not use this product** for persistent or chronic cough such as asthma, smoking or emphysema or if cough is accompanied by excessive mucus, unless directed by a licensed medical professional.

**A persistent cough may be a sign of a serious condition.**

**Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.

**Do not use if imprinted tamper band is broken or missing.**

**In case of emergency,** contact a medical professional or Poison Control Center immediately. Hyland's may also be contacted for emergency information about our products 24 hours a day, 7 days per week at (800) 624-9659.

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  
 Nux Vomica 6X HPUS.....tired, difficulty falling asleep, (0.0000016% Alkaloids, calculated) frequent waking  
 Phosphorus 12X HPUS.....hoarse/dry cough, nasal congestion, chest congestion  
 Pulsatilla 6X HPUS.....moist cough, cold, nasal congestion  
 Sulphur 12X HPUS .....chest congestion, nasal congestion, sneezing, runny nose

*"HPUS" indicates the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.*

**Uses** Temporarily relieves the symptoms of the common cold including cough, runny nose, sneezing, nasal and chest congestion, and sore throat with accompanying occasional sleeplessness.

**Warnings**

**As with any drug, ask a doctor before use if pregnant or breast-feeding. Consult a physician if:**  
 ■ Symptoms persist for more than 7 days or worsen ▶

information about our products 24 hours a day, 7 days per week at (800) 624-9659.

**Directions**

- Measure only with the dosing cup provided
- Do not use dosing cup with other products
- On dosing cup: mL = milliliter, tsp = teaspoon

Children 2 years to under 6 years	5 mL or 1 teaspoon at bedtime and every 4 hours during the night or as necessary
Children 6 years to under 12 years	10 mL or 2 teaspoons at bedtime and every 4 hours during the night or as necessary
Adults and children 12 years and over	15 mL or 3 teaspoons at bedtime and every 4 hours during the night or as necessary

**Inactive ingredients** Citric Acid, Glycerine, Glycyrrhiza Extract, Purified Water, Sodium Benzoate.

**Questions or comments?**  
 (800) 624-9659

DATOS DEL MEDICAMENTO EN EL INTERIOR DE LA CAJA.



PLEASE RECYCLE

4 KIDS COLD 'N COUGH DAYTIME/NIGHTTIME

Rev. 004

**4 KIDS COLD N COUGH DAY AND NIGHT VALUE PACK**

onion, calcium sulfide, sodium chloride, phosphorus, pulsatilla vulgaris, sulfur, goldenseal, strychnos nux-vomica seed, coffee bean, and chamomile kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-3177
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3177-1	1 in 1 CARTON; Type 0: Not a Combination Product	12/01/2013	

## 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 N 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
<b>PULSATILLA VULGARIS</b> (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	6 [hp_X] in 1 mL
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL
<b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
<b>ONION</b> (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
<b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a		



3075-1	Combination Product		
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/01/2008	

## Part 2 of 2

### NIGHTTIME COLD N COUGH 4 KIDS

onion, coffee bean, chamomile, calcium sulfide, goldenseal, sodium chloride, strychnos nux-vomica seed, phosphorus, pulsatilla vulgaris, and sulfur liquid

## Product Information

Item Code (Source)	NDC:54973-3098
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ONION</b> (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
<b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
<b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
<b>STRYCHNOS NUX-VOMICA SEED</b> (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	6 [hp_X] in 1 mL
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
<b>PULSATILLA VULGARIS</b> (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	6 [hp_X] in 1 mL
<b>COFFEE BEAN</b> (UNII: JFH385Y744) (COFFEE BEAN - UNII:JFH385Y744)	COFFEE BEAN	6 [hp_X] in 1 mL
<b>CHAMOMILE</b> (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	6 [hp_X] in 1 mL
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	
<b>WATER</b> (UNII: 059QF0K00R)	

<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3098-1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/01/2010	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/01/2013	

**Labeler** - Hylands Inc. (028570695)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		008316655	manufacture(54973-3177) , pack(54973-3177)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549198	manufacture(54973-3177) , pack(54973-3177) , label(54973-3177)

Revised: 5/2021

Hylands Inc.