

**BABY MUCUS PLUS COLD RELIEF DAYTIME AND NIGHTTIME-** calcium sulfide,phosphorus,sulfur,rumex crispus root,sodium chloride,arabica coffee bean,anemone pulsatilla,silicon dioxide, goldenseal,onion,bryonia alba root,euphrasia stricta and matricaria chamomilla  
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 Baby Mucus + Cold Relief Combo Pack Daytime & Nighttime**

**DAYTIME**

**Drug Facts**

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<b>Active ingredients</b>	<b>Purpose*</b>
Bryonia Alba 6X HPUS	stubborn mucus in throat, cough with mucus
Euphrasia Officinalis 6X HPUS	cough with mucus in chest
Hepar Sulph Calc 12X HPUS	cough up mucus, mucus rattle with cough, stubborn mucus in chest
Natrum Muriaticum 30X HPUS	accumulation of mucus in throat, cough up mucus
Phosphorus 30X HPUS	cough with mucus, chest congestion
Pulsatilla 6X HPUS	accumulation of mucus, discharge of mucus, loose cough
Rumex Crispus 6X HPUS	runny nose, sneezing
Silicea 12X HPUS	nasal congestion

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*HPUS" is the Homeopathic Pharmacopoeia of the United States.*

**Uses\***

- Helps temporarily relieve symptoms of common cold in children, including:
- accumulation of mucus in chest, throat or nose
- cough with mucus ■ runny nose ■ sneezing
- nasal or chest congestion

**Warnings**

**Ask a doctor before use if you have**

- persistent or chronic cough such as 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 72 hours or worsen. ■ inflammation, fever or infection is present or develops. ■ cough tends to recur or is accompanied by a fever, rash or persistent headache.

## Keep out of reach of children

### Directions

■ Use as directed. ■ Do not refrigerate. ■ Shake well before using.  
■ Measure only with the dosing syringe provided. ■ Do not use dosing syringe with other products. ■ On dosing syringe, mL = milliliter.

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Children under 6 months	Ask a doctor before use.
Children 6 months to under 1 year	2.5 mL up to 4 times per day (every 6 hours).
Children 1 year to under 3 years	5 mL up to 6 times per day (every 4 hours).

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### Inactive ingredients

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

## NIGHTTIME

### Drug Facts

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<b>Active ingredients</b>	<b>Purpose*</b>
Allium Cepa 6X HPUS	runny nose with mucus, hacking cough, sore throat
Bryonia Alba 6X HPUS	stubborn mucus in throat, cough with mucus
Chamomilla 3X HPUS	occasional sleeplessness
Coffea Cruda 3X HPUS	occasional sleeplessness
Euphrasia Offcinalis 6X HPUS	cough with mucus in chest
Hepar Sulph Calc 12X HPUS	cough up mucus, mucus rattle with cough, stubborn mucus in chest
Hydrastis 6X HPUS	cough with mucus, dry/sore throat, occasional sleeplessness due to mucus in throat
Natrum Muriaticum 6X HPUS	accumulation of mucus in throat, cough up mucus
Phosphorus 30X HPUS	cough with mucus, chest congestion
Pulsatilla 6X HPUS	accumulation of mucus, discharge of mucus, loose cough
Rumex Crispus 6X HPUS	runny nose, sneezing
Silicea 12X HPUS	nasal congestion

**"HPUS" is the Homeopathic Pharmacopoeia of the United States.**

**Uses\***

- Helps temporarily relieve symptoms of common cold in children at night, including:
- accumulation of mucus in chest, throat or nose
- cough with mucus ■ runny nose ■ sneezing
- 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 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 72 hours or worsen.
- inflammation, fever or infection is present or develops.
- cough tends to recur or is accompanied by a fever, rash or persistent headache.

**Keep out of reach of children**

**Directions**

- Use as directed. ■ Do not refrigerate. ■ Shake well before using. ■ Measure only with the dosing syringe provided. ■ Do not use dosing syringe with other products. ■ On dosing syringe, mL = milliliter.

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Children under 6 months	Ask a doctor before use.
Children 6 months to under 1 year	2.5 mL at bedtime and every 6 hours during the night until relieved.
Children 1 year to under 3 years	5 mL at bedtime and every 4 hours during the night until relieved.

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**Drug Facts (continued)**

**Inactive ingredients**

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

## **Questions?**

www.hylands.com or care@hylands.com

### **DAYTIME HOMEOPATHIC ACTIVE INGREDIENTS 10%**

### **NIGHTTIME HOMEOPATHIC ACTIVE INGREDIENTS 10%**

**\*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: accumulation of mucus in chest, throat or nose, cough with mucus, runny nose, sneezing, nasal or chest congestion, occasional sleeplessness.

## **Principal Display Panel**

### **Hyland's**

NATURALS™

### **•baby•**

### **Mucus + Cold Relief\***

### **COMBO PACK**

**NO SUGAR, PARABENS or DYES**

### **DAYTIME**

Mucus\*

Congestion\*

Runny Nose\*

Sneezing\*

Cough\*

### **NIGHTTIME**

Sleeplessness\*

Mucus\*

Congestion\*

Runny Nose\*

Sneezing\*

Cough\*

6+ MONTHS

DAYTIME - NO ALCOHOL

NIGHTTIME - LESS THAN 0.2% ALCOHOL

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

HOMEOPATHIC



**BABY MUCUS PLUS COLD RELIEF DAYTIME AND NIGHTTIME**  
 calcium sulfide, phosphorus, sulfur, rumex crispus root, sodium chloride, arabica coffee bean, anemone pulsatilla, silicon dioxide, goldenseal, onion, bryonia alba root, euphrasia stricta and matricaria chamomilla kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3374

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3374-1	1 in 1 CARTON; Type 0: Not a Combination Product	11/01/2018	

## Quantity of Parts

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

## Part 1 of 2

### BABY MUCUS PLUS COLD RELIEF

bryonia alba root, euphrasia stricta, calcium sulfide, sodium chloride, phosphorus, anemone pulsatilla, rumex crispus root, and silicon dioxide liquid

## Product Information

Item Code (Source)	NDC:54973-3284
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
<b>RUMEX CRISPUS ROOT</b> (UNII: 9N1RM2S62C) (RUMEX CRISPUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPUS ROOT	6 [hp_X] in 1 mL
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	6 [hp_X] in 1 mL
<b>EUPHRASIA STRICTA</b> (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	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	30 [hp_X] in 1 mL
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL

## Inactive Ingredients

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

<b>LICORICE</b> (UNII: 61ZBX54883)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3284-1	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		05/13/2016	

## Part 2 of 2

### BABY NIGHTTIME MUCUS PLUS COLD RELIEF

calcium sulfide,phosphorus,sulfur,rumex crispus root,sodium chloride,arabica coffee bean,anemone pulsatilla,silicon dioxide, goldenseal,onion,bryonia alba root,euphrasia stricta and matricaria chamomilla liquid

### Product Information

<b>Item Code (Source)</b>	NDC:54973-3371
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
<b>ONION</b> (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL
<b>BRYONIA ALBA ROOT</b> (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	6 [hp_X] in 1 mL
<b>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	3 [hp_X] in 1 mL
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL
<b>RUMEX CRISPUS ROOT</b> (UNII: 9N1RM2S62C) (RUMEX CRISPUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPUS ROOT	6 [hp_X] in 1 mL
<b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72) (ARABICA COFFEE BEAN -	ARABICA COFFEE	3 [hp_X]

UNII:3SW678MX72)	BEAN	in 1 mL
<b>ANEMONE PULSATILLA</b> (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
<b>EUPHRASIA STRICTA</b> (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	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>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3371-2	118 mL in 1 BOTTLE; 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	

### 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(54973-3374) , pack(54973-3374) , label(54973-3374)

