

**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 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 Baby Mucus + Cold Relief Nighttime**

***Purpose***

Relieves mucus, congestion, runny nose, sneezing, cough and occasional sleeplessness

***Drug Facts***

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<b><i>Active ingredients</i></b>	<b><i>Purpose</i></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 Officinalis 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
Sulfur 12X HPUS	cough with thick mucus, chest congestion, nasal congestion

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

***Uses***

■ Temporarily relieves 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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## **Inactive ingredients**

Citric Acid, Glycerine, Glycyrrhiza Extract, 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.**

**HOMEOPATHIC ACTIVE INGREDIENTS 10%**

Open for more snores!

Hyland's NATURALS™  
· baby ·  
**Mucus + Cold Relief**  
NIGHTTIME

Hyland's NATURALS™  
· baby ·  
**Mucus + Cold Relief**  
NIGHTTIME

NO SUGAR, PARABENS or DYES

Sleeplessness  
Mucus  
Congestion  
Runny Nose  
Sneezing  
Cough

6+ MONTHS

4 FL. OZ. (118 mL) LESS THAN 0.2% ALCOHOL | HOMEOPATHIC

Big cold symptoms can rock your baby out of their comfort zone at night. Naturally relieve mucus buildup and cold symptoms with our gentle and effective formula, so your baby (and you) can sleep easier.

Safe & Gentle  
Natural Active Ingredients  
No Side Effects

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.

**Drug Facts**

**Active Ingredients**

Active Ingredients	Purpose
Alburn Cypri 6X HPUS	runny nose with mucus, hacking cough, sore throat
Asterum Album 6X HPUS	stubborn mucus in throat, cough with mucus
Chamomilla 2X HPUS	occasional sleeplessness
Coffea Cruda 2X HPUS	occasional sleeplessness
Euphrasia Officinale 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
Nitrum 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
Silla 12X HPUS	nasal congestion
Sulphur 12X HPUS	cough with thick mucus, chest congestion, nasal congestion

**Use**  
Temporarily relieves 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 = milliter.  
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.

**Inactive Ingredients** Citric Acid, Glycerin, Glycyrrhiza Extract, Purified Water, Sodium Benzoate.

**Questions?** (800) 928-9859

\*CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED.  
DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING.

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

REV. 001

3 54973 33712 1 PLEASE RECYCLE



## 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3371
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

<b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] 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>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>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>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	3 [hp_X] in 1 mL
<b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	3 [hp_X] in 1 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	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>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3371-1	1 in 1 CARTON	11/01/2018	12/27/2021
1		148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3371-2	1 in 1 CARTON	11/01/2018	
2		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:54973-3371-3	2.5 mL in 1 PACKET; Type 0: Not a Combination Product	11/01/2018	12/27/2021

### 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(54973-3371) , pack(54973-3371) , label(54973-3371)

Revised: 4/2023

Hyland's Inc.