

BABY MUCUS COLD RELIEF DAY AND NIGHT VALUE PACK- bryonia alba root, euphrasia stricta, calcium sulfide, sodium chloride, phosphorus, anemone pulsatilla, rumex crispus root, silicon dioxide, onion, matricaria recutita, arabica coffee bean, goldenseal, strychnos nux-vomica seed, and sulfur Hyland's

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 Baby Mucus Cold Relief Day and Night Value Pack

DAYTIME

Drug Facts

Active ingredients	Purpose
Bryonia Alba 6X HPUS	stubborn mucus in throat, cough with yellowish 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 expectoration of yellow mucus, chest congestion
Pulsatilla 6X HPUS	accumulation of mucus, discharge of thick yellowish mucus, loose cough
Rumex Crispus 6X HPUS	runny nose, sneezing
Silicea 12X HPUS	nasal congestion

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

Uses

Temporarily relieves symptoms of colds, including accumulation of mucus in chest, throat and nose; cough with expectoration of thick, discolored mucus; runny nose, sneezing and nasal congestion.

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 Poison Control Center immediately.

Do not use this product for persistent or chronic cough such as asthma, smoking, 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 preprinted 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.

Directions

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

Children under 6 months of age	consult a licensed health care professional before using this product
Children 6 months to under 1 year of age	2.5 mL or ½ teaspoon up to 4 times daily (every 6 hours)
Children 1 to 3 years of age	5 mL or 1 teaspoon up to 6 times daily (every 4 hours)

Inactive ingredients

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

NIGHTTIME

Drug Facts

Active ingredients	Purpose
Allium Ceba 6X HPUS	runny nose with mucus, hacking cough, sore throat
Bryonia Alba 6X HPUS	stubborn mucus in throat, cough with yellowish mucus
Chamomilla 3X HPUS	irritability, fussiness, occasional sleeplessness
Coffea Cruda 3X HPUS	occasional sleeplessness, restlessness
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
Nux Vomica 6X HPUS	tired, difficulty falling asleep, (0.0000016% Alkaloids, calculated) frequent waking
Phosphorus 30X HPUS	cough with expectoration of yellow mucus, chest congestion
Pulsatilla 6X HPUS	accumulation of mucus, discharge of thick yellowish mucus, loose cough
Rumex Crispus 6X HPUS	runny nose and sneezing
Silicea 12X HPUS	nasal congestion
Sulphur 12X HPUS	cough with thick mucus, chest congestion, nasal congestion

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

Uses

Temporarily relieves symptoms of colds, including accumulation of mucus in chest, throat and nose; cough with expectoration of thick, discolored mucus; runny nose, sneezing, nasal congestion; and irritability, fussiness and occasional sleeplessness.

Warnings

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 Poison Control Center immediately.

Do not use this product for persistent or chronic cough such as asthma, smoking, 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 preprinted 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.

Directions

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

Children under 6 months of age	consult a licensed health care professional before using this product
Children 6 months to under 1 year of age	2.5 mL or ½ teaspoon up to 4 times daily (every 6 hours)
Children 1 to 3 years of age	5 mL or 1 teaspoon up to 6 times daily (every 4 hours)

Inactive ingredients

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

Questions or comments?

(800) 624-9659

PRINCIPAL DISPLAY PANEL - Kit Carton

New!

NDC 54973-3313-1

HOMEOPATHIC

Ages 6 months+

SINCE 1903

Hyland's®

Baby

Natural

Relief

Day & Night Value Pack

Daytime

Mucus +
Cold Relief

LOOSENS MUCUS,
RELIEF OF
CONGESTION,
RUNNY NOSE
AND COUGH*

ALCOHOL FREE

4 FL. OZ. (118 mL) Daytime

Nighttime

Mucus +
Cold Relief

LOOSENS MUCUS,
RELIEF OF
CONGESTION,
AND
OCCASIONAL
SLEEPLESSNESS
DUE TO COLDS*

LESS THAN 0.2% ALCOHOL

4 FL. OZ. (118 mL) Nighttime

► **No Artificial Flavors, Dyes or Parabens**

8 FL. OZ. (236 mL) TOTAL



Mucus + Cold Relief

Jarabe para resfríos

Day & Night Value Pack

NDC 54973-3313-1
HOMEOPATHIC
Ages 6 months+

New!



Natural
Relief

Day & Night Value Pack

CORTE AQUÍ



With a century of commitment to homeopathy, Hyland's provides quality and integrity across our entire family of products.

Daytime

Mucus +
Cold Relief

Jarabe para resfríos

LOOSENS MUCUS,
RELIEF OF
CONGESTION,
RUNNY NOSE
AND COUGH*

Aloja la mucosidad,
el alivio de la
congestión,
secreción
nasal y tos



ALCOHOL FREE

4 FL. OZ. (118 mL) Daytime

Nighttime

Mucus +
Cold Relief

Jarabe para resfríos de uso nocturno

LOOSENS MUCUS,
RELIEF OF
CONGESTION,
AND
OCCASIONAL
SLEEPLESSNESS
DUE TO COLDS*

Aloja la
mucosidad,
el alivio de la
congestión
y el insomnio
ocasional debido
al resfrío común



LESS THAN 0.2% ALCOHOL

4 FL. OZ. (118 mL) Nighttime

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

► No Artificial Flavors, Dyes or Parabens
No contiene saborizantes artificiales, tintes o parabenos

8 FL. OZ. (236 mL) TOTAL

*The uses for our products are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

DAYTIME

Drug Facts

Active ingredients

Purpose

Bryonia Alba 6X HPUS...stubborn mucus in throat, cough with yellowish 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
Natrium Muriaticum 30X HPUS...accumulation of mucus in throat, cough up mucus
Phosphorus 30X HPUS...cough with expectoration of yellow mucus, chest congestion
Pulsatilla 6X HPUS...accumulation of mucus, discharge of thick yellowish mucus, loose cough
Rumex Crispus 6X HPUS...runny nose, sneezing
Silicea 12X HPUS...nasal congestion
"HPUS" indicates that the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

Uses Temporarily relieves symptoms of colds, including accumulation of mucus in chest, throat and nose; cough with expectoration of thick, discolored mucus; runny nose, sneezing and nasal congestion.

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 Poison Control Center immediately.

Do not use this product for persistent or chronic cough such as asthma, smoking, 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 preprinted 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.

Directions

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

Drug Facts (continued)

Children under 6 months of age	consult a licensed health care professional before using this product
Children 6 months to under 1 year of age	2.5 mL or ½ teaspoon up to 4 times daily (every 6 hours)
Children 1 to 3 years of age	5 mL or 1 teaspoon up to 6 times daily (every 4 hours)

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

NIGHTTIME

Drug Facts

Active ingredients

Purpose

Allium Cepa 6X HPUS...runny nose with mucus, hacking cough, sore throat
Bryonia Alba 6X HPUS...stubborn mucus in throat, cough with yellowish mucus
Chamomilla 3X HPUS...irritability, fussiness, occasional sleeplessness
Coffea Cruda 3X HPUS...occasional sleeplessness, restlessness
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
Natrium Muriaticum 6X HPUS...accumulation of mucus in throat, cough up mucus
Nux Vomica 6X HPUS...tired, difficulty falling asleep, frequent waking
Phosphorus 30X HPUS...cough with expectoration of yellow mucus, chest congestion
Pulsatilla 6X HPUS...accumulation of mucus, discharge of thick yellowish mucus, loose cough
Rumex Crispus 6X HPUS...runny nose and sneezing
Silicea 12X HPUS...nasal congestion
Sulphur 12X HPUS...cough with thick mucus, chest congestion, nasal congestion

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

Uses Temporarily relieves symptoms of colds, including accumulation of mucus in chest, throat and nose; cough with expectoration of thick, discolored mucus; runny nose, sneezing, nasal congestion; and irritability, fussiness and occasional sleeplessness.

Drug Facts (continued)

Warnings

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 Poison Control Center immediately.

Do not use this product for persistent or chronic cough such as asthma, smoking, 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 preprinted 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.

Directions

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

Children under 6 months of age	consult a licensed health care professional before using this product
Children 6 months to under 1 year of age	2.5 mL or ½ teaspoon up to 4 times daily (every 6 hours)
Children 1 to 3 years of age	5 mL or 1 teaspoon up to 6 times daily (every 4 hours)

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

Questions or comments?

(800) 624-9659

Para más información en español visite:
www.miHylands.com

Datos del medicamento en el interior de la caja.



PLEASE RECYCLE

BABY
MUCUS+COLD RELIEF
DAY TIME/NIGHTTIME

Rev. 001

BABY MUCUS COLD RELIEF DAY AND NIGHT VALUE PACK

bryonia alba root, euphrasia stricta, calcium sulfide, sodium chloride, phosphorus, anemone pulsatilla, rumex crispus root, silicon dioxide, onion, matricaria recutita, arabica coffee bean, goldenseal, strychnos nux-vomica seed, and sulfur kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3313
---------------------	----------------	---------------------------	----------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3313-1	1 in 1 CARTON	03/30/2017	

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

BABY MUCUS AND 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
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	6 [hp_X] in 1 mL
EUPHRASIA STRICTA (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	30 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35IEV) (ANEMONE PULSATILLA -	ANEMONE	6 [hp_X]

UNII:I76KB35JEV)	PULSATILLA	in 1 mL
RUMEX CRISPUS ROOT (UNII: 9N1RM2S62C) (RUMEX CRISPUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPUS ROOT	6 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
LICORICE (UNII: 61ZBX54883)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

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 COLD RELIEF

onion, bryonia alba root, matricaria recutita, arabica coffee bean, euphrasia stricta, calcium sulfide, goldenseal, sodium chloride, strychnos nux-vomica seed, phosphorus, pulsatilla vulgaris, rumex crispus root, silicon dioxide, and sulfur liquid

Product Information

Item Code (Source)	NDC:54973-3251
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	6 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	6 [hp_X] in 1 mL

MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	3 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	3 [hp_X] in 1 mL
EUPHRASIA STRICTA (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X] in 1 mL
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
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	6 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
RUMEX CRISPUS ROOT (UNII: 9N1RM2S62C) (RUMEX CRISPUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPUS ROOT	6 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LICORICE (UNII: 61ZBX54883)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3251-1	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		12/28/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved homeopathic		03/30/2017	
---------------------------	--	------------	--

Labeler - Hyland's (028570695)

Establishment

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		008316655	manufacture(54973-3313, 54973-3284, 54973-3251) , pack(54973-3313, 54973-3284, 54973-3251) , label(54973-3313, 54973-3284, 54973-3251)

Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		117337220	pack(54973-3313, 54973-3284, 54973-3251)

Establishment

Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549198	manufacture(54973-3313) , pack(54973-3313) , label(54973-3313)

Revised: 7/2021

Hyland's