

CHILDRENS COLD AND MUCUS DAY AND NIGHT TWIN PACK- childrens cold and mucus day and night twin pack

Wal-Mart Stores, 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.

Equate Children's Cold & Mucus Day & Night Twin Pack

DAYTIME

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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	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.

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.

In case of emergency or accidental overdose,
contact a medical professional or Poison Control

Center immediately .

Drug Facts (continued)

Directions

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

Inactive ingredients

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

Other information

- Do not use if imprinted "SEALED FOR YOUR PROTECTION" tamper-evident bottle cap band is broken or missing.
- The inner packaged bottle is child-resistant.
- Store at room temperature.
- Do not refrigerate.

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
Natrum Muriaticum 6X 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
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 the symptoms of the common cold in children especially at night including accumulation of mucus in chest, throat and nose, cough with mucus, runny nose, sneezing, nasal congestion and occasional sleeplessness.

Drug Facts (continued)

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 a high fever (over 101°F)
- Cough tends to recur or is accompanied by a high fever, rash or persistent headache

Keep this and all medications out of the reach of children.

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.

In case of emergency or accidental overdose, contact a medical professional or Poison Control Center immediately.

Directions

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

Other information

- **Do not use if imprinted "SEALED FOR YOUR PROTECTION" tamper-evident bottle cap band is broken or missing.**
- **The inner packaged bottle is child-resistant.**
- **Store at room temperature.**
- **Do not refrigerate.**

Inactive ingredients

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

Principal Display Panel - Kit Carton

VALUE PACK

Equate™

NDC 49035-924-01

Compare to

Hyland's 4 Kids

Cold 'n Mucus

Value Pack

active

ingredients

Children's

Alcohol free, Sugar free, Dye-Free

Homeopathic

Cold & Mucus*

Daytime

Ages 2 to 12 years

For Temporary Relief of:

- Mucus & congestion
- Runny nose
- Cough

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

4 FL OZ (118mL) Daytime

8 FL OZ (236mL) TOTAL

Children's

Less than 0.2% Alcohol, Sugar free, Dye free

Homeopathic

Cold & Mucus*

Nighttime

Ages 2 to 12 years

For Temporary Relief of:

- Mucus & congestion
- Occasional sleeplessness
- Runny nose
- Cough

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

4 FL OZ (118mL) Nighttime



CHILDRENS COLD AND MUCUS DAY AND NIGHT TWIN PACK

childrens cold and mucus day and night twin pack kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-924

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-924-01	1 in 1 CARTON; Type 0: Not a Combination Product	07/01/2018	

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

Part 1 of 2**COLD AND MUCUS**

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:49035-926
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [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
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	6 [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
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-926-01	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		06/01/2018	

Part 2 of 2

CHILDRENS NIGHTTIME COLD AND MUCUS

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

Product Information

Item Code (Source)	NDC:49035-922
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
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	3 [hp_X] in 1 mL
RUMEX CRISPUS ROOT (UNII: 9N1RM2S62C) (RUMEX CRISPUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPUS ROOT	6 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	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
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	3 [hp_X] in 1 mL
EUPHRASIA STRICTA (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	30 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0K00R)	

SODIUM BENZOATE (UNII: OJ245FE5EU)				
LICORICE (UNII: 61ZBX54883)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-922-01	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		07/02/2018		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		07/01/2018		

Labeler - Wal-Mart Stores, Inc (051957769)

Establishment			
Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		008316655	manufacture(49035-924)

Establishment			
Name	Address	ID/FEI	Business Operations
Nexgen Pharma, Inc.		079424083	manufacture(49035-924) , pack(49035-924) , label(49035-924)

Establishment			
Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		876754375	manufacture(49035-924) , pack(49035-924) , label(49035-924)