

CHILDRENS NIGHTTIME COLD AND COUGH- onion, arabica coffee bean, calcium sulfide, phosphorus, matricaria chamomilla, anemone pulsatilla, goldenseal, sulfur and sodium chloride liquid

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 Nighttime Cold & Cough

Drug Facts

Active ingredients

<i>Active ingredients</i>	<i>Purpose</i>
Allium Cepa 6X HPUS	watery/runny nose, cold, hacking cough, sore throat
Chamomilla 6X HPUS	sensitive, irritable, fussy, nocturnal occasional sleeplessness
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
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 that 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 accompanying 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 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 health care professional.

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

Sore throat warning

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-evident bottle band is broken or missing.

The inner packaged bottle is child-resistant. In case of emergency, contact a medical professional or Poison Control Center immediately.

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 ery 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.

Principal Display Panel - 118 mL Bottle Label

NDC 49035-920-01

Compare to

Hyland's 4 Kids

Cold 'n Cough

Nighttime

Equate™

Alcohol Free, Sugar Free, Dye Free

Homeopathic

Childrens

Cold & Cough*

Nighttime

AGES 2 to 12 YEARS

For Temporary Relief of:

Chest congestion

Occasional sleeplessness

Runny nose

Sore throat

Cough

4 FL OZ (118mL)

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

Not FDA evaluated.

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Alcohol Free, Sugar Free, Dye Free

Homeopathic children's COLD & COUGH* Nighttime

AGES 2 to 12 YEARS

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- Occasional sleeplessness
- Runny nose
- Sore throat
- Sneezing
- Cough

4 FL OZ (118mL)

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WARNINGS/DIRECTIONS

REV. 001

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

Drug Facts (continued)

Not For Individual Retail Sale.

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments please call 1-888-287-1915.

DISTRIBUTED BY: Walman Inc., Bentonville, AR 72716

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CHILDRENS NIGHTTIME COLD AND COUGH

onion, arabica coffee bean, calcium sulfide, phosphorus, matricaria chamomilla, anemone pulsatilla, goldenseal, sulfur and sodium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-920
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
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	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	12 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-920-01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/02/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/02/2018	

Labeler - Wal-Mart Stores, Inc (051957769)**Establishment**

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		008316655	manufacture(49035-920) , pack(49035-920) , label(49035-920)

Establishment

Name	Address	ID/FEI	Business Operations
NEXGEN PHARMA, INC.		079424083	manufacture(49035-920) , pack(49035-920) , label(49035-920)

Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		117337220	manufacture(49035-920) , pack(49035-920) , label(49035-920)

Revised: 7/2018

Wal-Mart Stores, Inc